

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOPURE SECURITIES
LITIGATION

Civil Action No. 03-12628-NG

**PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS
THE CONSOLIDATED AMENDED COMPLAINT**

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INTRODUCTION

Plaintiffs respectfully submit this memorandum of law in opposition to the motions to dismiss the Consolidated Amended Complaint (“Complaint”), filed by defendants Biopure Corporation, Thomas A. Moore, Carl W. Rausch , Howard P. Richman, Charles A. Sanders and J. Richard Crout (collectively referred to herein as the “Biopure Defendants”) and by defendant Ronald F. Richards’ (“Richards”).¹

STATEMENT OF FACTS

This action is brought on behalf of investors who purchased Biopure Corporation (“Biopure” or the “Company”) stock during the period from March 17, 2003 through December 24, 2003 (the “Class Period”), and a sub-class of investors who bought contemporaneously with defendants sale of their Biopure stock, and arises out of defendants’ materially false and misleading statements and omissions concerning Biopure and the status of its effort to obtain regulatory approval from the U.S Food & Drug Administration (the “FDA”) to market its blood substitute, Hemopure, for treatment of human patients.² Plaintiffs allege that defendants misled investors by failing to disclose that the FDA had advised Biopure it had safety concerns about Hemopure based on its review of adverse event data from a previously submitted clinical study,

¹ The Biopure Defendants and Richards have each submitted a memorandum of law in support of their respective motions. The Biopure Defendants’ memorandum of law is cited to herein as “Biopure Mem. at ____.” Defendant Richards’ memorandum of law is cited to herein as “Richards Mem. at ____.”

²Defendants include Biopure and certain of its officers and directors, including: Thomas A. Moore (“Moore”), President and CEO of the Company; Carl W. Rausch (“Rausch”), a director and Biopure’s Vice Chairman and Chief Technical Officer; Ronald F. Richards (“Richards”), Biopure’s Chief Financial Officer and Senior Vice President-Business Development; Charles A. Sanders (“Sanders”), a director and Chairman of the Board of Biopure; Richard Crout (“Crout”), a director of Biopure; and Howard P. Richman (“Richman”), Biopure’s Senior Vice President if Regulatory Affairs and Operations during part of the Class Period.

which caused the FDA to halt further human clinical trials and delay the approval process, and cast serious doubt on the likelihood of obtaining FDA approval.

Biopure develops, manufactures and markets oxygen therapeutics, for both human and veterinary use, designed to serve as an alternative to red blood cell transfusions and for use in the treatment of other critical care conditions. ¶2.³ The Company develops and manufactures two products: Hemopure, for human use, and Oxyglobin, for veterinary use. *Id.* Oxyglobin is approved in the United States for use in dogs. *Id.* Hemopure is approved in South Africa for use in severely anemic surgery patients. *Id.* It is not approved for human use in the United States or any other country. *Id.*

On July 31, 2002, Biopure submitted a biologic license application (“BLA”) to the FDA, seeking regulatory approval to market Hemopure in the United States for patients undergoing orthopedic surgery (the “Hemopure BLA”). ¶25. As part of the usual procedure in seeking such approval, Biopure submitted as part of the Hemopure BLA data from the Phase III clinical trials which it had conducted on the use of Hemopure for patients undergoing orthopedic surgery. *Id.*

In Biopure’s quarterly report filed on Form 10-Q for the period ended January 31, 2003 (the “January 2003 10-Q”), filed on March 17, 2003 at the start of the Class Period, defendants underscored the crucial importance to the Company of obtaining regulatory approval to market Hemopure for use in the treatment of human patients. ¶24. In the January 2003 10-Q, defendants state:

³References to the Complaint are cited herein as “¶____.”

Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financing, strategic alliances and interest income. We have not been profitable since inception and had an accumulated deficit of \$392,713,000 as of January 31, 2003. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure in Europe and other markets and pre-marketing expenditures for Hemopure....

* * * *

The completed Phase III orthopedic surgery trial cost approximately \$37,000,000 over the four years from protocol development to final report. These trial costs include costs incurred at nearly 50 hospitals, trial site monitoring, data management, regulatory consulting, statistical analysis, medical writing and clinical materials and supplies as well as Company personnel engaged in these activities. Costs incurred in filing the BLA include Company personnel and payments to third parties for manufacturing process documentation, medical consultants, regulatory consultants, integrating the safety and efficacy data bases for all clinical trials and pre-clinical studies. Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation....

Id.

In September 2002, Biopure received a grant from the U.S. Department of the Army for the purpose of conducting clinical trials of Hemopure for treatment of certain trauma patients. ¶26. In Biopure's Annual Report for its fiscal year 2002, filed with the SEC on Form 10-K on January 29, 2003 (the "2002 10-K"), defendants state: "***The Company has identified trauma as its next clinical development priority*** and is working with a committee of independent civilian and military trauma experts to broaden its trauma program." *Id.* (emphasis added).

In March 2003, Biopure submitted a "Trauma Study Protocol," in which the

Company advised the FDA that it intended to conduct a Phase II clinical study of Hemopure for use in trauma victims (the “Trauma Trial”). ¶28. **Immediately** thereafter, the FDA informed defendants that the proposed Trauma Trial could not go forward. *Id.* The FDA advised defendants that it had placed a clinical hold on their proposed Trauma Trial due to safety concerns (the “FDA’s Safety Concerns”) arising from the FDA’s review of adverse event data from the Company’s Phase III orthopedic surgery trial, which was submitted with the Hemopure BLA. *Id.*

The FDA’s Safety Concerns, which were communicated to defendants in March 2003, put defendants on notice that approval of the Hemopure BLA was in serious doubt and would, unquestionably, be delayed beyond the time frames that defendants had previously communicated to the investing public. ¶31. Nevertheless, throughout the Class Period, in numerous public filings, statements and press releases issued on behalf of the Company, defendants intentionally failed to disclose this material, adverse information to the investing public. *Id.* Indeed, as detailed below, the Company’s affirmative statements throughout the Class Period concerning the Hemopure BLA and the proposed Trauma Trial were materially misleading in that they failed to disclose the FDA’s Safety Concerns, which caused the FDA to put a hold on further clinical trials of Hemopure. *Id.*

In the January 2003 10-Q, which was filed on March 17, 2003, while purporting to disclose risks faced by Biopure and its shareholders, defendants made the following false and deceptive statement concerning the Phase III Hemopure clinical study:

If We Fail to Obtain FDA Approval We Cannot Market Hemopure in the United States

We will not be able to market Hemopure in the United States until we receive FDA approval. We have filed an application for approval with the FDA, and the application was accepted for review on October 1, 2002.

We believe that our completed pivotal Phase III clinical studies are consistent with the FDA's most recent guidance on the design and efficacy and safety endpoints required for approval of products such as Hemopure for use in surgical indications.

¶41 (emphasis added). These statements were materially false and misleading in light of the fact that defendants concealed the fact that the FDA had advised Biopure of the FDA's Safety Concerns. ¶43. Defendants repeated these same materially false and misleading statements, almost verbatim, in registration statements which Biopure subsequently filed with the SEC (the "Registration Statements").⁴ ¶44. The Registration Statements were signed by all but one of the individual defendants.⁵ ¶45.

Moreover, despite the fact that defendants knew about the FDA's Safety Concerns and that the FDA had placed the proposed Trauma Trial on hold, defendants continued to make statements anticipating FDA approval as if nothing had happened. For instance. In the January 2003 10-Q, defendants made the following misleading and deceptive statements about Biopure and the Hemopure BLA:

Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation. These BLA support costs were \$2,232,000 for the first fiscal

⁴The Registration Statements included: Post-Effective Amendment No. 2 to Form S-3 registration statement filed with the SEC on April 11, 2003; Post Effective Amendment No. 1 to Form S-3 registration statement filed with the SEC on April 16, 2003; Form S-3 Registration Statement filed with the SEC on June 19, 2003; and Amendment No. 1 to Form S-3 registration statement filed with the SEC on July 2, 2003. ¶44.

⁵Defendants Moore, Rausch, Richards, Sanders and Crout each signed the Registration Statements on behalf of the Company. ¶44. Defendant Richman was the only individual defendant who did not sign the registration statements. *Id.*

quarter of 2003 and are expected to continue at approximately the same level **until the middle of this calendar year, when the Company is hopeful that it will receive action by the FDA on the BLA.**

* * * *

If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004. We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure.

¶45 (emphasis added).

Defendant Richards signed the January 2003 10-Q and defendants Moore and Richards certified that they had reviewed it and that it did not contain “any untrue statement of a material fact **or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading** with respect to the period covered by this quarterly report.”

¶46 (emphasis added). Defendants Moore and Richards further certified that they had designed “disclosure controls and procedures” which would have ensured that defendants would have learned of the FDA’s Safety Concerns so that defendants could have timely and properly disclosed those concerns to the investing public in the January 2003 10-Q. ¶47. Among other things, Defendants Moore and Richards certified that:

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14©) and 15d-14©) under the Securities Exchange Act of 1934,⁶ as amended

⁶Exchange Act Rules 13a - 14(c) and 15d -14(c) define “disclosure controls and procedures” as follows:

(the “Exchange Act”)) within 90 days of the filing date of this Quarterly Report on Form 10-Q (the “Evaluation Date”). **Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.**

¶48 (emphasis added).

On March 25, 2003, Biopure issued a press release announcing it had raised \$13.4 million in a stock offering which contained the following deceptive and misleading statements regarding the Hemopure BLA and the Trauma Trial:

Biopure’s application to market Hemopure in the United States for [acutely anemic surgical patients] undergoing elective orthopedic surgery is currently being reviewed by the U.S. Food and Drug Administration....

.... Completion of the pivotal RESUS clinical trial of Hemopure in trauma is contingent upon further funding

¶49 (emphasis added).

On April 24, 2003, Biopure and Moore issued another misleading and deceptive press release regarding the Hemopure BLA, in which Moore stated that “[b]ased on our interactions with the FDA and the guidelines in the Prescription Drug Users Fee Act, we’re hopeful the [FDA] will complete its review of our marketing application mid-year.”

...controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is recorded, processed, summarized and reported, within the time periods specified in the Commission’s rules and forms. **Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer’s management, including its principal executive officer or officers and principal financial officer or officers...** (Emphasis added.)

¶50. Neither press release disclosed the FDA's Safety Concerns nor the fact that the FDA's Safety Concerns caused it to halt Biopure's proposed Trauma Trial and was likely to delay or impede FDA approval of the Hemopure BLA. *Id.*

In May 2003, Biopure responded to the FDA's safety concerns regarding the Hemopure by filing additional information (the "BLA Amendment"). ¶51. In response, the FDA extended its review period an additional 90 days through August 29, 2003. *Id.* Thereafter, the FDA on at least two occasions, the last in a letter dated July 30, 2003, refused to lift its hold on the Company's proposed Trauma Trial. ¶52. Yet, defendants continued to make false and misleading public statements regarding the Hemopure BLA and the BLA Amendment, by failing to disclose the FDA's Safety Concerns and that, as a result, the FDA had placed a hold on the Trauma Trial. *Id.*

For instance, on May 22, 2003, defendants issued a false and misleading press release stating, among other things:

Based upon FDA performance goals and guidelines in the Prescription Drug User Fee Act (PUDFA), **Biopure is hopeful that in mid 2003 the FDA will complete its review and act on Biopure's biologic license application (BLA) to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery....Biopure has responded to all questions raised by the FDA to date.**

¶53 (emphasis added). That same day, defendants Moore, Richards and Richman participated on behalf of Biopure in an analysts' conference call for institutional investors. ¶54. During the May 22 conference call, defendants made various false and misleading statements concerning the Hemopure BLA. For example, defendant Moore stated:

- [W]e continue to be very hopeful of an [FDA] response on our [BLA] by mid-year or sooner, and we continue to not be aware of any issues with that application at this time....
- On FDA, I'll just reiterate, I guess, at our last quarter we ... had answered all FDA questions and **we were unaware of any major issues. Fundamentally we're in the same place now....**
- **We continue to say we are not aware of anything that would cause undue delay [in receiving a response from the FDA to the Hemopure BLA]....**

¶55 (emphasis added).⁷

On May 30, 2003, defendants issued a press release announcing that the FDA had extended its time to act on the Hemopure BLA until August 29, 2003, in which they continued to fail to disclose the FDA's Safety Concerns and sought to downplay the delay in obtaining FDA approval of the Hemopure BLA:

As part of the normal review process, Biopure has responded to FDA questions regarding the application. The agency has classified the latest responses submitted in mid-May 2003 as additional analyses of previously submitted data, which under FDA standard operating procedures automatically provides the agency up to three months beyond the original action due date to review the data. **This type of action is not unusual**—the last 11 standard BLAs accepted for review by the FDA have undergone a 13-month review.

¶58 (emphasis added). In the press release, Moore stated:

We're very pleased with the FDA's progress in reviewing our application **We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available as an alternative to red blood cell transfusion. We're also continuing our preparations to roll out the product to leading orthopedic surgery centers following approval.**

⁷All of the defendants' statements during the May 22 conference call were made available to the investing public via a live webcast that was available through the Biopure website and archived for 30 days. ¶57.

¶59 (emphasis added).

During another analysts' conference call on May 30, 2003, in which defendants Moore, Richman and Richards participated, Moore was asked about the BLA Amendment in May 2003. ¶61. Specifically, Moore was asked why Biopure was still being asked to provide additional information to the FDA 9-1/2 months after the original Hemopure BLA was submitted. ¶61. Moore responded that the BLA Amendment "was some additional analysis which we provided on data that was already in the BLA. At the time, we didn't consider it a major amendment to the BLA but the FDA looked at that as a reason to extend [the deadline for approval].... *Id.*

When asked why there had been no disclosure about the BLA amendment when it was submitted, Moore responded that "**we were simply responding to a new set of questions from the FDA.** It did not involve any new data. And so, frankly, it was well within the range of other questions we've answered in the past. When we made that response, we didn't characterize it as a major amendment to the BLA...." *Id.* (emphasis added). When he was pressed to be more specific, Moore declined and said:

It's actually—it was a dialogue really about how to look at the clinical data. As you know, there are various analyses used to look at our efficacy and safety data and **we just had a dialogue about the different ways you could look at the analyses that are performed on the data.** And that's really as far as we want to characterize it.

Id. (emphasis added).

When asked why the FDA's questions required a three month delay, Moore said:

...the FDA chose to look at this as a major amendment to the BLA...if we submit new information about any aspect of the product, whether it's pivotal or not, they can decide that that's a reason to go for the extension. **So I'm not sure whether or not the data we submitted, we did not**

submit any new data, whether there was a reason for the extension of whether the echo simply needed an extension, period.

Id. (emphasis added). These statements were false and misleading since defendants concealed the fact that the delays were the result of the FDA's Safety Concerns, which also had not been disclosed. ¶62.

On June 16, 2003, Biopure filed its quarterly report on Form 10-Q with the SEC for the period ended April 30, 2003 (the "April 2003 10-Q"), in which it reiterated the purported risks of failure to obtain FDA approval of the Hemopure BLA that were disclosed in the previously filed January 2003 10-Q and registration statements. ¶63.

The April 2003 10-Q went on to make the following misleading statement:

If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004. We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure....

Id. (emphasis added). The April 2003 10-Q was signed by Richards and contained the same certifications by Moore and Richards that were contained in the January 2003 10-Q. ¶64. These statements were false, deceptive and misleading because while they purported to disclose the risks of failing to obtain FDA approval of the Hemopure BLA, defendants failed to disclose the existing FDA's Safety Concerns, and which had in fact caused a delay in and even posed a threat to obtaining such approval. ¶65.

On August 1, 2003, Biopure issued a press release in which it disclosed that the FDA had completed its review of the Hemopure BLA and had suspended its "review clock" pending the receipt of additional information from the Company. ¶66. The

August 1 Press Release stated:

Biopure Corporation (BPUR) announced today that the U.S. Food and Drug Administration (FDA) has completed its review of the company's biologic license application (BLA) for Hemopure® [hemoglobin gulatmer - 250 (bovine)] and issued a letter requesting additional information. The letter focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling. It does not request additional clinical trials. Biopure has applied to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.

With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock until Biopure submits a complete response.

"We're encouraged that the FDA has finished its review and provided comprehensive feedback in advance of the formal action due date. By maintaining thirty days on the review clock, the FDA is encouraging us to work with them to complete the approval process as quickly as possible," said Biopure President and CEO Thomas A. Moore. "We'll work with the Agency to address the remaining questions and will provide our answers as expeditiously as possible."

Id.

The statements in the August 1 Press Release were false and misleading because defendants failed, once again, to disclose the FDA's Safety Concerns. ¶67. The marketplace, unaware of the FDA's Safety Concerns, responded positively to the news and Biopure's stock price reached as high as \$9.03 and closed at \$7.30 a share, up 22% over the previous day's closing price. ¶68. Thereafter, Biopure's stock price continued to climb, reaching \$8.12 a share on August 20, 2003. ¶69.

On August 21, 2003, Biopure issued another press release concerning the FDA's review of the Hemopure BLA, which stated in part:

On July 30th, the FDA sent Biopure a letter stating that the agency has

completed its review of the company's BLA to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The letter requests additional information and suspends the BLA review clock with 30 days remaining in the original review cycle. It does not request additional clinical trials. Biopure is preparing its response, which, when submitted, will restart the review clock. "We've developed many of our initial responses and so far we feel we will be prepared to answer FDA's questions," said Moore. "We have an opportunity to answer all of the Agency's remaining questions before it acts on our application, so we want to be sure we're fully meeting the FDA's needs. Therefore, we are requesting a meeting with the FDA in September. The Agency is allowing Biopure to set the agenda for this meeting, which will enable us to request any clarifications we need to complete our responses. The timing for when we'll submit our complete response to the FDA will be driven by the guidance we receive during this meeting."

¶70. That same day, defendants Moore, Richards and Richman participated in an analysts conference call. ¶71.⁸ During the August 21 conference call, defendants made false and misleading statements and gave answer to analysts' questions in which they admitted that the investing public believed their prior representations concerning Biopure and the status of the FDA's review of the Hemopure BLA, which later proved to be false, deceptive and misleading. ¶72. For example, defendant Moore made the following statements during the August 21 conference call:

In July we completed a public offering raising \$17.2 million...In conducting this raise, Chief Financial Officers Ron Richards and I presented to 62 funds in person over a three-week period. This is the most extensive presentation of the company ever, surpassing even the effort behind the IPO launch. **Subsequent share price performance suggests we're beginning to establish an understanding of the exciting future potential for Hemopure** as both a treatment for anemia associated with surgery, and an oxygen therapeutic for use in trauma, surgical ischemias

⁸Like the May 22 conference call, analysts and institutional investors could participate in the August 21 conference call and the investing public could listen to the call live and access it through Biopure's website for a period of time thereafter. *Id.*

and cancer therapy.

* * *

We've not initiated human clinical trials in trauma with the military or for that matter on the civilian side as yet. So, we hope to get started on that ASAP...but I don't believe human trials will begin until after we have completed our answers to the BLA.

Id. (emphasis added). As a result, Biopure's stock price once again rose to \$8.25 per share at the close of trading.

On September 17, 2003, defendant Moore gave a presentation concerning Biopure and the Hemopure BLA at the ThinkEquity Partners Growth Conference at the Omni Hotel in San Francisco, California, which Biopure had publicized in a September 10, 2003 press release. ¶¶73-74. Moore made the following statement, among others, which was disseminated to the investing public on Biopure's website:

...From a safety standpoint, our agreement with FDA was that the primary safety endpoint would be based on a peak analysis which was a separate analysis of the data done by an independent and blinded medical panel. That panel concluded that our product was not inferior to red blood cells in respect to overall medical risk. **This is not the only way the agency looks at safety but it is the primary safety endpoint.**

¶76 (emphasis added). Moore's entire presentation concerning Biopure and the status of the FDA's review of the Hemopure BLA was false and misleading given defendants' continuing failure to disclose the FDA's Safety Concerns during that presentation. ¶¶77-78.

On September 25, 2003, defendant Moore gave a similar presentation at the UBS Global Life Sciences Conference, which Biopure had publicized in a September 18, 2003 press release. ¶¶79-80. During his presentation, Moore made various

statements concerning Biopure and the Hemopure BLA, which again were disseminated to the investing public on Biopure's website. ¶80. Among other things, Moore stated that the results of a blinded analysis of Biopure's "pivotal trial" by a panel of doctors "compared the accumulative scores between our products and red blood cells **and achieved a safety objective which was to confirm that our product was not inferior to red blood cells with respect to overall medical risks.**" ¶81 (emphasis added). These statements, which bore directly on whether the Hemopure trial achieved the primary safety endpoint required for FDA approval, were false, deceptive and misleading because defendants continued to conceal the FDA's Safety Concerns from the investing public. ¶82.

On October 30, 2003, before the stock market opened, Biopure issued a press release that, while not disclosing the FDA's Safety Concerns to the investing public, did disclose some of the consequences thereof, including the fact that the FDA would not act on the Hemopure BLA for at least another nine months until sometime after June 30, 2004. ¶83. This in turn had significant, negative financial implications for Biopure, some of which were outlined in the October 30 press release. ¶83. The press release also disclosed that defendant Richman had left the Company "to pursue other interests." *Id.*

That same day, defendants Moore and Richards participated in an analysts conference call, in which they discussed Biopure's "regulatory and operating plans."⁹ ¶87. The statements made during the October 30 conference call were false, deceptive

⁹Like the May 22 and August 21 conference calls, members of the investing public could listen to the October 30 conference call live and access it on Biopure's website for a period of time thereafter. *Id.*

and misleading in that defendants still did not disclose the FDA's safety concerns. ¶87. For example, when asked about safety, Moore responded only that Biopure's experience using Hemopure with humans in South Africa had been "very positive from the standpoint that we have had very good experience with the patients and developed what we consider a **very good safety record** with the product." ¶88 (emphasis added).

Although defendants failed to disclose the FDA's Safety Concerns during the October 30 conference call, as noted above, they did disclose some of the significant, material adverse consequences resulting therefrom. ¶89. As a result of those disclosures, on October 30, 2003, Biopure's stock price dropped as low as \$2.80 and closed at \$3.68 per share, a drop of over 39% from the previous day's closing price. *Id.* By November 3, 2003, Biopure's stock price had dropped to \$3.20, down 47% from its closing price of \$6.05 on October 29, 2003, and continued to decline thereafter. ¶91.

By December 24, 2003, the closing price of Biopure stock had declined to just \$2.82 a share. ¶92. After the close of trading on December 24, 2003, Biopure announced that some of the defendants had received a "Wells Notice" concerning the SEC staff's preliminary recommendation to bring civil injunctive proceedings against them regarding the Company's disclosures about its communications with the FDA regarding the proposed clinical trauma trial and the Hemopure BLA. ¶33. The December 24 press release stated in relevant part:

CAMBRIDGE, Mass., Dec 24, 2003 ... Biopure Corporation (BLUR) reported that on December 22, 2003, it received a "Wells Notice" from the staff of the Securities and Exchange Commission (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the company.... The company's chief executive officer [the Defendant Moore] and its former senior vice president of Regulatory and Operations [the Defendant Richman] also

received Wells Notices.

... the notices relate to the company's disclosures concerning its communications with the Food and Drug Administration (FDA) about a trauma study protocol the company submitted to the Agency in March 2003 and about the company's biologics license application (BLA) for Hemopure® [hemoglobin glutamer - 250 (bovine)]....

Biopure submitted the trauma protocol for a Phase II clinical trial of Hemopure for the treatment of hemorrhagic shock casualties in the hospital setting, where red blood cell transfusions are available....

After the in-hospital trauma protocol was submitted to the FDA...**the Agency placed a clinical hold on the proposed trauma trial due to safety concerns. The FDA referred to a review of adverse event data from the company's Phase III orthopedic surgery trial, which was submitted in the BLA....**

In May 2003, Biopure responded to the FDA's clinical hold and also filed the response as a BLA amendment because it discussed data previously submitted with the BLA. That amendment resulted in the FDA extending its BLA review period up to 90 days, as previously announced on May 30, 2003.... After the company's responses, the FDA has twice declined to lift the clinical hold, most recently in a letter dated July 30, 2003. This letter is separate from the FDA complete response letter Biopure received on that date in response to its BLA for orthopedic surgery. The questions in the FDA's trauma letter were the same as some of the questions in the BLA complete response letter....

Id. (emphasis added). In the December 24 press release, defendants disclosed to the investing public for the first time the FDA's Safety Concerns, and that those concerns had resulted in the delay of the Trauma Trial and had placed the FDA's approval of the Hemopure BLA in jeopardy. ¶¶34-36.

On April 30, 2004, Biopure announced that the SEC had issued four additional Wells Notices, indicating that the SEC staff had made a preliminary decision to recommend that the SEC bring civil injunctive actions against defendants Sanders, Crout and Rausch, as well as Biopure's General Counsel, for violations of the federal

securities laws, which the Company believed were similarly related to defendants' disclosures concerning the Company's communications with the FDA about the Hemopure BLA. ¶ 93. The April 30, 2004 press release noted that the Wells Notices gave the individuals notified "an opportunity to respond in writing before the SEC staff formally decides what action, if any, to recommend." *Id.* To date, the FDA has not acted on the Hemopure BLA or removed the clinical hold on the trauma clinical trial, and each of the Wells Notices remains outstanding. Currently, Biopure stock trades at well under \$1.00 per share.

ARGUMENT

I. APPROPRIATE STANDARDS OF REVIEW

A. Standard of Review on a Motion to Dismiss

On a motion to dismiss, the court must accept all allegations of the complaint as true, and "must draw all reasonable inferences from the particular allegations in the plaintiff's favor." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 78 (1st Cir. 2002). A court may dismiss a complaint only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Roeder v. Alpha Industries, Inc.*, 814 F.2d 22, 25 (1st Cir. 1987). The proper standard is for the court to determine whether "the complaint as a whole is sufficiently particular." *In re Cabletron Systems, Inc.*, 311 F.3d 11. 32 (1st Cir. 2002).

In addition, the procedural posture of the case should be considered in determining whether to deny a motion to dismiss. See *id.* at 33 ("under our circuit law, the procedural posture of the case matters, and we will scrutinize a post-discovery

motion to dismiss even more stringently than a pre-discovery motion"). Where, as here, there has been no discovery,¹⁰ a plaintiff cannot be held to "a standard that would effectively require them, pre-discovery, to plead evidence." *Cooperman v. Individual, Inc.*, 171 F.3d 43, 48-49 (1st Cir. 1999) (citing *Shaw v. Digital Equipment Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996)). See also *Aldridge*, 284 F.3d at 81 (distinguishing *Greebel v. FTP Software, Inc.*, 194 F.3d 185 (1st Cir. 1999), on basis of difference in amount of discovery); *Maldonado v. Dominguez*, 137 F.3d 1, 9 (1st Cir. 1998) (noting limit on expectations of securities fraud pleadings when discovery is incomplete).

B. Standard for Section 10(b) and Rule 10b-5 Liability and the PSLRA

To state a claim under Section 10(b) and SEC Rule 10b-5, plaintiffs must plead, with sufficient particularity, that defendants "made a false statement or omitted a material fact, with the requisite scienter, and that the plaintiff's reliance on this statement or omission cause the plaintiff's injury." *In re Transkaryotic Therapies, Inc. Securities Litigation*, 319 F.Supp. 2d 152, 158 (D. Mass. 2004) (quoting *Gross v. Summa Four, Inc.*, 93 F.3d 987, 992 (1st Cir. 1992)).

Under Fed. R. Civ. P. 9(b) and the PSLRA, plaintiffs must identify "each statement alleged to be misleading," "the reason or reasons why the statement is misleading," and, with respect to allegations based upon information and belief, state "with particularity all facts on which that belief is based." 15 U.S.C. §78u-4(B)(1)(B). See *Aldridge*, 284 F.3d at 78 (plaintiff must set forth "each allegedly misleading statement or omission, including its time, place and content," and facts to show why

¹⁰Pursuant to the PSLRA, in a securities class action such as this, all discovery is automatically stayed pending resolution of the defendants' motion to dismiss the complaint. 15 U.S.C. 78u-4(b)(3)(B).

statements or omissions were misleading). In addition, plaintiffs must allege sufficient facts to show that inferences of scienter “are both reasonable and strong.” *Aldridge*, 284 F.3d at 78 (citation omitted). The First Circuit has emphasized, however, that the PSLRA pleading requirements “do not change the standard of review for a motion to dismiss,” in that “even under the PSLRA, the district court, on a motion to dismiss, must draw all reasonable inferences from the particular allegations in the plaintiff’s favor, while at the same time requiring the plaintiff to show a strong inference of scienter.” *Id.*

“A fact is material if there is a substantial likelihood ‘that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the “total mix” of information made available.’” *In re Sepracor, Inc. Securities Litigation*, 308 F. Supp.2d 20, 27 (D. Mass. 2004) (quoting *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). Moreover, “[w]hether a statement is misleading and whether adverse facts are adequately disclosed” ordinarily should not be resolved on a motion to dismiss, but instead “are generally questions that should be left to the trier of fact.” *In re PLC Systems, Inc. Securities Litigation*, 41 F. Supp.2d 106, 116 (D. Mass. 1999) (citing *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995)). Indeed, “[o]nly if ‘reasonable minds’ could not disagree that the challenged statements were not misleading should the district court dismiss under 12(b)(6).” *PLC*, 41 F. Supp. 2d at 116 (quoting *Warshaw v. Xoma Corp.*, 74 F.3d 955, 959 (9th Cir. 1996)).

“In general, the materiality of a statement or omission is a question of fact that should normally be left to a jury rather than resolved by the court on a motion to dismiss.” *Cabletron*, 311 F.3d at 34. “Thus, [courts] review the complaint only to determine that it pleads the existence of such statements and presents a plausible jury question of

materiality.” *Id.*

II. THE COMPLAINT SUFFICIENTLY ALLEGES DEFENDANTS’ MATERIAL MISREPRESENTATIONS AND OMISSIONS

Defendants’ arguments to the contrary notwithstanding, the Complaint alleges in sufficient detail that, during the Class Period, defendants issued statements containing material misrepresentations and omissions, which misled the investing public concerning the true status of the Hemopure BLA. Specifically, defendants misrepresented the status of the FDA’s approval of the Hemopure BLA and the proposed clinical trauma trial, by failing to disclose the FDA’s safety concerns regarding Hemopure arising from its review of Biopure’s orthopedic surgery trial and that the FDA had put a clinical hold on the trauma trial. Moreover, even after disclosing a delay in the FDA’s decision on the Hemopure BLA, defendants continued to mislead investors by failing to disclose that the delay resulted from the FDA’s safety concerns and that those concerns made approval less likely.

A. Defendants Had a Duty to Disclose the FDA’s Safety Concerns About Hemopure

Contrary to defendants’ arguments in their respective briefs (Biopure Mem. at 13-16; Richards Mem. at 18), defendants had a duty to disclose the FDA’s safety concerns about Hemopure in its public statements and press releases concerning Biopure and the Hemopure BLA. Because some statements, “although literally accurate, can become, through their context and manner of presentation, devices which mislead investors ... the disclosure required by securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective

buyers.” *Lucia v. Prospect Street High Income Portfolio*, 36 F.3d 170, 175 (1st Cir. 1994); accord *In re Biogen Securities Litigation*, 179 F.R.D. 25, 34-35 (D. Mass. 1997). Moreover, “[w]hen a corporation does make a disclosure – whether it be voluntary or required – there is a duty to make it complete and accurate.” *Roeder*, 814 F.2d at 26; accord *Gross*, 93 F.3d at 992; *Biogen*, 179 F.R.D. at 34. “While Rule 10b-5 does not create an affirmative duty of disclosure, ‘such a duty may arise if . . . a corporation has previously made a statement of material fact that is either false, inaccurate, incomplete, or misleading in light of the undisclosed information.’” *Sepracor*, 308 F. Supp.2d at 27 (quoting *Gross*, 93 F.3d at 992). Although this duty to disclose does not require the disclosure of all other facts “that, too, would be interesting, market-wise,” it does require the disclosure of facts “that are needed so that what was revealed would not be ‘so incomplete as to mislead.’” *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990); accord *Gross*, 93 F.3d at 992.

Plaintiffs have sufficiently alleged facts to show that defendants failure to disclose the FDA’s Safety Concerns is actionable under Section 10(b) and Rule 10b-5 and the PSLRA.¹¹ As alleged in the Complaint, during the Class Period, defendants never disclosed the FDA’s Safety Concerns about Hemopure, and that those undisclosed Safety Concerns caused the FDA to place a hold on Biopure’s proposed Trauma Trial,

¹¹As demonstrated below, plaintiffs have properly alleged Rule 10b-5 claims against defendants. Accordingly, defendants’ motions to dismiss with respect to plaintiffs’ Section 20(a) claims should be denied. See, e.g., *Elysian Fed. Sav. Bank v. First Interregional Equity Corp.*, 713 F. Supp. 737, 751 n.18 (D.N.J. 1989).

delay the approval process, and cast serious doubt on the likelihood of approval.¹² ¶31. Even after defendants disclosed that the FDA had suspended the review deadline while it sought additional information regarding the Hemopure BLA in October 2003 – seven months after learning about the FDA’s Safety Concerns – defendants never disclosed the true reasons for the delay. ¶¶62, 67, 77, 82, 85, 88. In fact, it was only after the SEC had served defendants with Wells Notices in December 2003 concerning defendants’ disclosure about their communications with the FDA concerning the Hemopure BLA that defendants disclosed the fact that the delay in the approval process was the result of the FDA’s Safety Concerns. ¶¶32, 33.

It is well established that liability may be imposed under Rule 10b-5 where defendants makes a materially false or misleading statement or omission about the safety profile of a medical product, including the results of clinical studies. See, e.g., *Sepracor*, 308 F. Supp. 2d at 28 (held failure to disclose cardiac side effects of new drug was actionable in light of FDA’s previously stated “zero tolerance” policy concerning such side effects); *In re Amylin Pharmaceuticals, Inc. Securities Litigation*, C.A. No. 01CV1455 BTM, 2003 U.S. Dist. LEXIS 7667 (S.D. Cal. May 1, 2003) (in denying motion to reconsider denial of motion to dismiss court held that false and

¹²Defendants’ argument inappropriately relies on materials outside the scope of the complaint, including, among other things, a news article concerning the FDA approval process, to demonstrate that the existence of the FDA’s safety concerns merely reflects the FDA’s evaluation of risk versus benefit and therefore does not constitute an obstacle to approval. See Defendants’ Memorandum, at 5-6, and Defendants’ Appendix, Exhibit 11. Such materials are not properly considered on a motion to dismiss in the First Circuit. *Shaw*, 82 F.3d at 1214 n.25; see also *In re Allaire Corp. Securities Litigation*, 224 F.Supp.2d 319, 327-328 (D. Mass. 2002) (“Defendants offer facts that they assert contradict the Plaintiffs’ assertions. This, however, misapprehends the pleading posture. In a motion to dismiss, the Court assumes that all of the pled facts are true. The appropriate place to proffer contradictory facts is on a motion for summary judgment, which occurs after discovery.”). Accordingly, the sections of the Defendant’s pleadings quoting a news article or other materials not referenced or discussed in the Complaint should be stricken and not considered by this Court.

misleading statements about data and information supporting FDA application for approval of new drug is actionable); *In re Viropharma, Inc. Securities Litigation*, C.A. No. 02-1267, 2003 U.S. Dist. LEXIS 5623 (E.D. Pa. Apr. 7, 2003) (court denied motion to dismiss where FDA rejected new drug application based on allegations about false and misleading statements concerning drug studies that had been conducted); *In re Neopharm, Inc. Securities Litigation*, C.A. No. 02 CV 2976, 2003 U.S. Dist LEXIS 1862, *43-44 (N.D. Ill. Feb. 7, 2003) (court denied motion to dismiss because plaintiffs alleged strong circumstantial evidence that defendants knew results of Phase II testing at beginning of class period); *In re Cell Pathways, Inc. Securities Litigation*, C.A. No. 99-752, 2000 U.S. Dist. LEXIS 8584 (E.D. Pa. June 21, 2000) (court denied motion to dismiss because plaintiffs adequately alleged problems with company's clinical trials that made their public statements misleading); *PLC*, 41 F. Supp. 2d 106 (court denied motion to dismiss based on finding that plaintiffs sufficiently alleged defendants misrepresented facts about clinical trials of medical device).

It is also well established that defendants can be held liable for failing to disclose FDA concerns about clinical studies conducted in connection with applications for regulatory approval, which make any of their public statements misleading. See *Transkaryotic*, 319 F. Supp. 2d at 159-160 (court denied motion to dismiss because defendants failed to disclose FDA's critique of the company's drug studies as flawed and for failing to show efficacy); *Biogen*, 179 F.R.D. at 31-32 (on motion for summary judgment court held defendants' statement claiming positive results of drug study were actionable because defendants did not disclose FDA's concerns about shortcomings of study and failure to reach primary endpoint); see also *In re British Biotech*, Release No.

41505, 1999SEC LEXIS 1162 (June 10, 1999) (SEC concluded that defendants' statements claiming that clinical studies demonstrated efficacy without also disclosing FDA's contrary opinion were actionable).

Drawing all reasonable inferences from the particular allegations of fact in favor of plaintiffs, *Aldridge*, 284 F.3d at 78, it is substantially likely—in fact it is a virtual certainty—that a reasonable investor would view the FDA's safety concerns about Hemopure and its resulting decision to suspend review of the Hemopure BLA and place a hold on Biopure's proposed clinical trauma trial as having altered the “total mix” of information made available about Biopure and the Hemopure BLA. *Basic*, 485 U.S. 231-32. See *Transkaryotic*, 319 F. Supp. 2d at 160-161 (held failure to disclose FDA's serious criticism of study methodology was a material omission). Cf. *Sepracor*, 308 F. Supp. 2d at 28 (“If, as plaintiffs allege, the FDA had previously stated a ‘zero tolerance’ policy for any cardiac side effects, including those found in animal studies, then information about cardiac side effects in animal studies of [the drug] would ‘have been viewed by the reasonable investor as having significantly altered to “total mix” if information made available’”) (citing *Basic*, 485 U.S. 231-32). Since its inception, Biopure had focused primarily on developing Hemopure for human use in the United States. ¶24. Hemopure was a “first in its class” drug that had only been approved for human use in South Africa and nowhere else. *Id.* By its own admission, Biopure had never made a profit, had an accumulated deficit of almost \$400 million before the Class Period even began, and expected to incur additional operating losses in connection with obtaining approval for Hemopure in Europe and elsewhere. *Id.* In fact, the FDA's Safety Concerns which had previously been communicated to defendants, were based

on adverse events in the orthopedic surgery trial, which alone had cost about \$37 million over the course of 4 years. *Id.* Thus, in light of the history and nature of Biopure's business, the most critical and material information about the Company during the Class Period was the status of the Hemopure BLA, including all facts which bore on when and whether the FDA would (or would not) approve it, including, in particular, the FDA's Safety Concerns and its negative impact on FDA approval. ¶27. Defendants deliberately and intentionally withheld this information in order to mislead the investing public about the future prospects of Biopure and the likelihood that FDA would approve the Hemopure BLA.

The Court's decision in *Transkaryotic* is instructive. There, plaintiffs' Rule 10b-5 claim was based on defendants' failure to disclose that the FDA had sent the company a letter informing defendants that it had reservations about flaws in the clinical studies submitted in support of its application for regulatory approval of Replagal to treat Fabry Disease. 319 F. Supp. 2d at 159. Specifically, the plaintiff alleged that the FDA in a letter to the company advised defendants that TKT's clinical studies did not show efficacy, that the company would have to conduct additional studies to address the efficacy issues, and that the methodology of the studies was flawed. *Id.* In that case, the defendants argued that they were not required to disclose the FDA's concerns about the previously submitted clinical studies because they subsequently disclosed that the FDA had denied marketing approval for Replagal and requested additional data. In rejecting defendants' argument, the Court in *In re Transkaryotic* held that the complaint stated a claim that defendants "made material omissions in withholding the FDA's opinion that TKT's studies did not show efficacy and were methodologically flawed and

that in order to generate acceptable data, TKT would have to start over from scratch.”

Id.

The facts of this case are just as compelling as those in *Transkaryotic*, if not more so. In *Transkaryotic*, the court ruled that, even though defendants had disclosed the fact that the FDA had actually denied marketing approval of Replagal and asked for additional information, their failure to disclose the **reasons** for the FDA’s action – i.e., the FDA’s opinion that the company’s clinical studies were flawed and did not show efficacy – was actionable. *Id.* In the present case, although defendants ultimately disclosed delays in the FDA’s approval of the Hemopure BLA, they materially misled investors by failing to disclose the **primary reason** that the FDA approval process was delayed, i.e., the FDA’s Safety Concerns, as well as the fact that ultimate FDA approval was threatened as a result.

In addition, defendants’ reliance upon *In re MedImmune, Inc. Securities Litigation*, 873 F. Supp. 953 (D. Md. 1995), is misplaced. Biopure Mem. at 14-15. In *MedImmune*, the court allowed a motion to dismiss Rule 10b-5 claims based on defendants’ failure to disclose “random or sporadic” questions from the FDA during the approval process on grounds that “[m]any, if not all, questions presumably get answered in the process.” *Id.* at 966. The same court, however, denied defendants’ motion to dismiss with respect to statements that “could possibly have misled an investor into thinking that the review process remained totally problem-free” because, in that case, the FDA had communicated to the defendants concerns about the efficacy of the drug “in such a way as to indicate that ultimate approval of [the drug] looked

problematic" *Id.* at 968. Thus, where, as in the present case, defendants' failure to disclose FDA concerns which cast doubt upon obtaining approval of a BLA in statements regarding the status of the approval process are actionable under Rule 10b-5. See *Transkaryotic*, 319 F. Supp. 2d at 160-161, n.9 (distinguishing *MedImmune*, *supra*, and denying motion to dismiss claims that defendants failed to disclose FDA's concerns that methodological flaws in studies indicated doubt about ultimate approval). As in *MedImmune*, in the present case, defendants compounded their deliberately misleading failure to disclose the FDA's Safety Concerns that delayed FDA approval of the Hemopure BLA by seeking to minimize those delays, e.g., by calling them "routine" and "not unusual." See ¶¶58-66, 70-72.

Similarly, defendants' reliance on the Court's decision in *Biogen*, 179 F.R.D. 25, is also misplaced. Biopure Mem. at 14-15. In *Biogen*, the company sought FDA approval of an anti-clotting drug. *Id.* at 30. Several months after the Phase II clinical trials on the drug failed to show efficacy, when the principal investigators in the study publicly disclosed this failure, securities analysts downgraded the company's stock, causing the price to fall. *Id.* at 31. On a summary judgment motion,¹³ the court in *Biogen* held that, because defendants had disclosed "the most relevant and disappointing aspect" – i.e., the failure to show efficacy – defendants were under no further obligation to disclose additional information about the status of obtaining FDA

¹³As noted above, the Court should also take into account the procedural posture of the case and not require plaintiffs in this case to plead "evidence" prior to conducting any discovery. *Cooperman*, 171 F.3d at 48-49; *Aldridge*, 284 F.3d at 81; *Maldonado*, 137 F.3d at 9. Accordingly, since there is a stay on discovery pending resolution of defendants' motions to dismiss pursuant to the PSLRA, the *Biogen* decision, which was decided on a summary judgment motion after plaintiffs had an opportunity to complete their discovery, is inapposite.

approval. *Id.* at 39. Unlike *Biogen*, in this case, defendants failed to disclose “the most relevant and disappointing aspect” about the Hemopure BLA, which was that the FDA had suspended its review and asked for additional information from Biopure and had placed a hold on the proposed Trauma Trial due to the FDA’s Safety Concerns based on averse results in the clinical study submitted with the original application.¹⁴

Finally, the decision in *Chu v. Sabratek*, 100 F. Supp. 2d 827, 834 (N.D. Ill. 2000), upon which defendants also rely (Biopure Mem. at 15), is inapposite. In *Sabratek*, plaintiffs alleged that defendants failed to disclose the FDA’s warnings that the company’s production of “flush syringes” failed to comply with federal regulations and requested that the company submit an application to continue production. After the FDA denied approval to continue producing the syringes, defendants suspended production, causing the company’s stock price to drop. As the court noted in that case, the company’s “regulatory difficulties with the FDA were known to public investors.” *Id.* at 834. The court therefore found that no further disclosure was required. *Id.* By contrast, in the present case, the FDA’s Safety Concerns were hidden from the investing public throughout the Class Period.¹⁵

¹⁴Similarly, the Court in *Transkaryotic* distinguished the holding in *Biogen* that defendants, having disclosed that the company’s clinical studies had failed to show efficacy, were under no obligation to provide additional disclosures about the FDA approval process for precisely that reason. There, the Court noted that the “[t]he ‘most relevant and disappointing aspect’ of the *Biogen* study was its failure to show efficacy – precisely the information that [Transkaryotic] did not disclose in the present case.”

Transkaryotic, 319 F. Supp. 2d at 159-160. In rejecting the defendants’ argument that their disclosure that the FDA had denied approval of Replagal would inform a reasonable investor that the company’s studies failed to show efficacy, the Court in *Transkaryotic* noted that, unlike in *Biogen*, analysts did not even mention lack of efficacy or equate the FDA’s denial of approval in any way with a failure to show efficacy. *Id.*

¹⁵Moreover, in *Sabratek*, the court found that the defendants’ representations that they had not violated any federal regulations were true, since the FDA had told the company it would take no action against production and distribution of the syringes unless it rejected the company’s application. *Id.* at 835.

B. Defendants' Statements Concerning the Status of the FDA Approval Process and Their Communications with the FDA Regarding the Hemopure BLA Were False, Deceptive and Misleading

Plaintiffs have also adequately alleged that, by failing to disclose the FDA's Safety Concerns, defendants' public statements concerning the status of the FDA approval process and their communications with the FDA regarding the Hemopure BLA were also actionable under Rule 10b-5. As alleged in detail in the Complaint, despite knowing about the FDA's Safety Concerns, Defendants deliberately misled investors by making a number of statements concerning Biopure and the Hemopure BLA that, in light of the fact that the FDA's undisclosed concerns delayed and had placed FDA approval of the Hemopure BLA in jeopardy, were materially false, deceptive or misleading.

1. Defendants' Materially False and Misleading Statements Concerning the Risks Associated with Failing To Obtain FDA Approval of Hemopure in Biopure's Public Filings with the SEC

As alleged in the Complaint, Biopure's January 2003 10-Q, April 2003 10-Q and the Registration Statements filed with the SEC each contained a virtually identical disclaimer, purporting to disclose the risks associated with failure to obtain FDA approval. ¶¶41, 44, 63. In each such disclaimer, defendants state that while the Company cannot market Hemopure in the United States without FDA approval, "[w]e believe that our completed pivotal Phase III clinical trials are consistent with the FDA's

In accordance with the FDA's representation, the company continued to produce the syringes until the FDA denied its application, at which point it suspended production. By contrast, in the present case, the FDA had put a clinical hold on any conducting further trials of Hemopure in humans, based on the FDA's Safety Concerns, a fact which defendants failed to disclose to the investing public.

most recent guidance on the design and efficacy and safety endpoints required for approval of products such as Hemopure for use in surgical indications.” ¶¶41, 44, 63. The disclaimers go on to state that “the FDA could change its view” and request changes in study design, additional information or clinical studies prior to granting approval. ¶41 n.1. Defendants also stated that the process of obtaining FDA approval was both time-consuming and costly “with no assurance if ultimate success.” While purporting to disclose the risks faced by the Company and its investors, these disclaimers were false, deceptive and misleading because they failed to disclose the crucial fact that defendants had already been advised that the FDA had halted further clinical testing of Hemopure because of the FDA’s Safety Concerns, which threatened to delay or even derail the approval process.

In *Transkaryotic*, the court held that similar disclaimers concerning the risk of failure to obtain FDA approval for Replagal contained in the company’s public filings were materially misleading in light of the defendants’ failure to disclose that the FDA had requested additional clinical trials arising out of its “serious criticisms” of the company’s efficacy trials. 319 F. Supp. 2d at 161 & n.10. Each such disclaimer stated that the FDA might “request additional information, possibly including data from additional clinical trials.” *Id.* at 161 n.10. The court in *Transkaryotic* found these statements materially false and misleading because “[s]uch language is materially different from the fact that the FDA had, in essence, already made that request; indeed, the phrasing conceivably implies that the FDA’s earlier request for additional information did not include a request for data from additional studies.” *Id.* Similarly, in the present case, defendants’ qualifying statement that “the FDA **could** change its view” was

materially misleading in that it failed to disclose the FDA's Safety Concerns and falsely implied that the FDA had expressed no such concerns about the safety of Hemopure based on the previously submitted clinical trials.

2. Defendants' Materially False and Misleading Statements Concerning the Safety of Hemopure

During the Class Period, defendants made a number of statements concerning the safety of Hemopure which were materially false and misleading in light of the FDA's Safety Concerns that were hidden from the investing public. As noted above, in the Company's public filings with the SEC, defendants state their belief that the completed clinical studies were "consistent with the FDA's guidance on ... safety endpoints for approval of Hemopure." ¶¶41, 44, 63. In addition, despite knowing about the FDA's Safety Concerns and its resulting refusal to lift its clinical hold on additional human testing, defendants made the following additional false and misleading statements regarding the safety of Hemopure during the Class Periods:

- On September 17, 2003, at the ThinkEquity Growth Partners conference, defendant Moore represented that Biopure had reached the primary safety endpoint required for FDA approval, based upon an independent blind analysis by a medical panel which concluded that Hemopure "was not inferior to red blood cells in respect to overall medical risk." ¶76.
- On September 25, 2003, at the UBS Global Life Sciences Conference, Moore reiterated his statement that Biopure had reached its primary safety endpoint based on the panel's conclusion that Hemopure was "not inferior to red blood cells with respect to overall medical risks," again, without disclosing the FDA's Safety Concerns. ¶81.
- During the October 30 analysts conference call, defendant Moore stated that Biopure had developed "**a very good safety record**" for the use of Hemopure with humans. ¶88 (emphasis added).

Defendants' statements concerning the safety of Hemopure were materially

false, deceptive and misleading because, at the time they were made, defendants *knew* that the FDA had halted further human testing and delayed the approval process based on the FDA's Safety Concerns. Whether defendants, in fact, believed Hemopure to be safe for use in humans is beside the point, since the issue was not safety, *per se*, but whether the FDA would approve the Hemopure BLA in light of the FDA's Safety Concerns which defendants hid from the investing public. As the Court explained in *Transkaryotic*:

Defendants further contend that TKT's optimistic statements about efficacy are not actionable because TKT had "ample reasonable basis" for its belief that its studies showed efficacy—namely, the publication of TKT's test results in two respected medical journals as well as Replagal's approval in the European Union, Norway, Iceland, New Zealand, the Czech Republic, Switzerland, Israel, Australia and Romania. At most, defendants argue, there was a "subjective scientific disagreement" over the efficacy of Replagal. **But, this was not a mere scientific disagreement—the issue was [FDA] approval to market the drug.** Moreover, the failure to disclose the concerns [about efficacy] raised in the highly negative Complete Review Letter—the conclusions of which were echoed by FDA's second Complete Review Letter at the end of 2002—makes TKT's trumpeting of Replagal's efficacy arguably misleading. **The existence of a subjective scientific disagreement over the efficacy of Replagal should have been made known to investors, particularly where the FDA comprised the side that strenuously contested the drug's effectiveness. As alleged by plaintiffs, the FDA's findings as to efficacy were material and should have been disclosed.**

319 F. Supp. 2d at 160 (emphasis added).

3. Defendants' Statements Unduly Optimistic Statements Anticipating FDA Approval and Concerning Biopure's Future Prospects Were False and Misleading

Despite knowing about the FDA's Safety Concerns and its negative impact on the likelihood of obtaining FDA approval to market Hemopure, defendants deliberately

misled investors by repeatedly making unduly optimistic statements anticipating FDA approval and Biopure's expected future revenues from marketing Hemopure in the United States. For example, at various points throughout the Class Period, defendants made the following statements:

- In the January 2004 10-Q, defendants stated that it expected the costs associated with obtaining FDA approval of Hemopure "are expected to continue at approximately the same level ***until the middle of this calendar year, when the Company is hopeful that it will receive action by the FDA on the BLA.***" ¶45.
- In both the January 2003 10-Q and the April 2003 10-Q, defendants state that "***If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from the project in fiscal 2004....***" ¶45, 63.
- On April 24, 2003, defendants issued a press release in which Moore stated that "***Based on our interactions with the FDA and the guidelines in the Prescription Drug Users Fee Act, we're hopeful the agency will complete its review of our marketing application mid-year.***" ¶50.
- On May 23, 2003, defendants issued a press release which stated that "***Biopure is hopeful that in mid 2003 the FDA will complete its review and act on [the Hemopure BLA]***" ¶53.
- On May 30, 2003, defendants issued a press release in which defendant Moore stated "We're very pleased with the FDA's progress in reviewing our application.... ***We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available.... We're continuing preparations to roll out the product to lead orthopedic surgery centers following approval.***" ¶58.
- At an analysts conference call on August 21, 2003 to discuss the FDA's suspension of the approval process, defendant Moore trumpeted Biopure's stock price performance after raising \$17.2 million in a stock offering in July 2003 and indicated it suggested that defendants were "beginning to establish an understanding of the exciting future potential for Hemopure...." ¶72.

Defendants' statements anticipating FDA approval by mid-year in 2003 and the

Company's expected future revenues from marketing Hemopure were materially misleading in light of the fact that defendants knew that the FDA had already halted Biopure's proposed Trauma Trial and asked the Company for additional information based on the FDA's Safety Concerns about adverse events data in the orthopedic surgery trial, and that the approval process would likely be delayed as a result.

In a similar vein, on March 25, 2003, defendants issued a press release which stated that the Company expected to receive \$4 million in funding from the U.S. Navy in addition to the previously announced \$4.9 million grant from the Army to conduct the Trauma Trial. ¶49. In the March 25, 2003 press release, defendants stated that "***Completion of the pivotal RESUS clinical trial of Hemopure in trauma is contingent upon further funding***" *Id.* This statement, too, was materially false and misleading, because defendants knew, but failed to disclose, that the FDA had halted the Trauma Trial on account of the FDA's Safety Concerns and that Biopure's proposed trial would not be completed unless and until the FDA lifted its clinical hold on further testing.

4. Defendants' False and Misleading Statements Concerning the Status of FDA Approval and Their Communications with the FDA Concerning the Hemopure BLA

After disclosing that the FDA had delayed the approval process and requested additional information, defendants repeatedly sought to reassure investors by minimizing the important and effect of such a delay by the agency. By continuing to conceal the FDA's Safety Concerns and the resulting negative impact on the approval process, defendants deliberately misled investors by making the following false and

misleading statements:

- On May 30, 2003, defendants issued a press release announcing that the FDA extended the review deadline by 90 days, and that “as part of the normal review process, Biopure has responded to FDA questions regarding the application.” ¶58. The May 30, 2003 press release also states that “***This type of action is not unusual***—the last 11 standard BLAs accepted for review by the FDA have undergone a 13-month review.” *Id.*
- During the May 30, 2003 conference call, when questioned by analysts who expressed concern about the FDA’s extension of time and request for additional information, defendant Moore actively sought to downplay those concerns. ¶61. For instance, Moore stated that Biopure had merely submitted “additional analysis” of previously submitted date and that it did “not involve any new data.” *Id.* In addition, Moore denied that defendants considered their submission of additional information to be a “major amendment” to the Hemopure BLA, even though the FDA was treating it as such. *Id.* In addition, when asked to be more specific, Moore refused and characterized defendants’ communications with the FDA as merely a “dialogue” about nothing more than how to look at the clinical data on safety and efficacy. *Id.*
- On August 1, 2003, defendants issued a press release announcing that the FDA had suspended its review of the Hemopure BLA and sent a letter requesting additional information that “focuses primarily on ***clarification of clinical and preclinical data*** and includes some comments on labeling.” ¶66. The August 1, 2003 press release also states that “With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock ***until Biopure submits a complete response.***” *Id.* In addition, in the August 1 press release, defendant Moore sought to reassure investors by stating, among other things, that by suspending the review clock, “the FDA is encouraging us to work with them to complete the approval process as quickly as possible.” *Id.*
- On August 21, 2003, defendants issued another press release stating that on July 30, 2003, the FDA informed Biopure that it had completed its review and had suspended the review clock pending receipt of a complete response the agency’s request for additional information from Biopure. ¶70. The August 21, 2003 press release emphasized that the FDA had not requested any additional clinical trials and that defendants had “developed many of our initial responses and so far we feel prepared to answer FDA’s questions.” *Id.* The press release further stated that the

FDA had granted the Company' request for a meeting to enable defendants "to request any clarifications we need to complete our responses" and that "[t]he timing for when we'll submit our complete response to the FDA will be driven by the guidance we receive during this meeting." *Id.*

- At an analyst conference call on August 21, 2003, when asked about Biopure's proposed Trauma Trial, Moore admitted the Trauma Trial probably would not start until after Biopure completed its response to the FDA's request for additional information. *Id.* Neither Moore nor the other defendants who participated in the August 21 conference call disclosed the FDA's Safety Concerns or fact that the FDA had halted the proposed Trauma Trial based on those undisclosed concerns. ¶72.
- On October 30, 2003, defendants issued a press release announcing that the FDA would not act on the Hemopure BLA until sometime after June 30, 2003. ¶84. While the October 31, 2003 did disclose the severe financial consequences of this further unexpected delay, it failed to disclose the FDA's Safety Concerns which had caused the delay and jeopardized Biopure's prospects for obtaining FDA approval. *Id.* Instead, the press release contained a statement from defendant Moore that defendants "view the agency's questions as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible." *Id.*

In addition, despite knowing about the FDA's Safety Concerns and their negative impact on Biopure and the Hemopure BLA, defendants denied that they were aware of any issues that threatened to delay or derail the FDA approval process. For instance, during an analysts conference call on May 22, 2003, when asked about the status of the Hemopure BLA, defendant Moore continued to express optimism about obtaining FDA approval within the original review deadline and falsely stated that defendants were unaware of any issues that would stand in the way. See ¶¶55.a.-c. ("we continue to be very hopeful of an [FDA] response on our [BLA] by mid-year or sooner, and **we continue to not be aware of any major issues with that application at this time**"; "at

our last quarter we ... had answered all FDA questions and ***we are not aware of any major issues. Fundamentally, we are in the same place now***"; "We continue to say we are not aware of anything that would cause undue delay [in receiving a response from the FDA to the Hemopure BLA]").¹⁶

The fact that defendants subsequently disclosed that the FDA had delayed approval and requested additional information regarding the Hemopure BLA does not satisfy defendants' obligation to disclose the FDA's Safety Concerns. In *Transkaryotic*, the court rejected the defendants' argument they had satisfied their duty to disclose that the FDA had advised the company of the need for new clinical trials with the statement that the FDA had "asked for further explanation in several areas and requested additional data." *Id.* As the Court stated, a statement that the FDA had requested "additional data" was "a far cry from disclosing that FDA had in fact recommended additional clinical studies." *Id.* Similarly, in the present case, defendants failed to satisfy their duty to disclose the FDA's Safety Concerns, and its adverse impact on the approval process, by stating that the reason for the delay in approval was merely because the FDA had requested "additional information." Rather, defendants had a duty to disclose the ***reason*** that the FDA had requested additional information, that is, the FDA's Safety Concerns.

The *MedImmune* decision, rather than supporting defendants' argument that the Complaint fails to allege that the statements made were false and misleading, actually

¹⁶Defendants Richman and Richards can be held accountable for these statements since they participated in the call and they acquiesced in and did not in any way seek to correct those statements. ¶56.

demonstrates that, by failing to disclose the FDA's safety concerns about Hemopure, defendants' statements regarding the FDA's delay in approval of the Hemopure BLA in the present case are actionable. In *MedImmune*, the court found that two statements made by defendants to reassure defendants about an FDA delay **were actionable** because, in the words of the court:

Arguably, both of these statements were attempts to reassure the public that FDA's postponement of the drug review was not a cause for concern and simply a matter of routine. But the comments of Dorothy Scott, staff fellow at FDA's Office of Blood Research and Review, reported in Biocentury the day after the Advisory Committee vote, suggest that, ***by the time of the statements, FDA may have taken a harder line and MedImmune may in fact have been aware of considerably more serious reasons for the postponement.*** Scott reportedly said that FDA had notified MedImmune of problems with randomization "as early as August, when a letter was sent out asking for more information." ***If FDA had indeed communicated such concern to MedImmune and did so in such a way as to indicate that ultimate approval of [the drug] looked problematic, then Hockmeyer's statements could possibly have misled an investor*** into thinking that the review process remained totally problem-free. These statements, therefore, remain in the case for purposes of discovery and trial.

873 F. Supp. at 967-968 (emphasis added).

Similarly, in the present case, after learning of the FDA's Safety Concerns, defendants not only failed to disclose them, but also actively sought to reassure investors by creating the false impression that the FDA approval process was trouble free, even after disclosing that the FDA first delayed and then suspended its review of the Hemopure BLA. ¶¶58, 62, 66, 70, 72, 84. Defendants also sought to "spin" the delay in the FDA's approval by asserting that by suspending its review, "the FDA is encouraging us to work with them to complete the approval process as quickly as possible." ¶66. Biopure's rising stock price confirms that the market was misled. ¶67.

None of the defendants ever bothered to correct these false impressions, which they had themselves deliberately created, and therefore had a duty to correct. See *Biogen*, 179 F.R.D. at 34 ("A speaker has a 'duty to correct' misinformation when a disclosure is, in fact, misleading ***when made***").

Likewise, the decision in *Biogen*, upon which defendants also rely, actually supports a finding that defendants' failure to disclose the FDA's Safety Concerns in their statements regarding the status of the FDA approval process and their communications with the FDA about the Hemopure BLA were actionable under Rule 10b-5. In *Biogen*, the company learned that its drug study failed to show efficacy on its prospectively defined primary endpoint in September 1993. 179 F.R.D. at 30. Nevertheless, four months later on January 11, 1994, Biogen's CEO issued a statement claiming that the study had produced good results, without disclosing that the study failed to reach the primary endpoint. *Id.* at 30-31. The *Biogen* court found this statement both materially misleading and actionable because:

When the record is viewed in the light most favorable to the plaintiffs, a reasonable jury could conclude that the January 11, 1994 statement portraying [the drug study] as a successful trial significantly altered the total mix of information then available on the market. Although the plethora of analysts reports issued on the evening of January 11 and in the days following did not specifically reference [the CEO's] remarks they echoed [his] upbeat predictions and specifically referred to the release of positive [drug study] data in March. The price of Biogen stock went up 12 percent....

Id. at 36. In the present case, like in *Biogen*, despite knowing that the FDA's undisclosed Safety Concerns had delayed the FDA approval process, defendants sought to reassure investors about those delays and deliberately misled investors by, among other things, representing that the delays in the approval process were more or

less routine under the circumstances. As the Court held in *Biogen*, defendants in the present case had a duty to disclose the FDA's Safety Concerns in order to make their statements concerning the safety of Hemopure not misleading in light of those concerns.

5. Defendants Moore and Richards Falsely Certified That Biopure's Public Filings with the SEC Did Not Contain Any Misleading Statements or Omissions

Pursuant to the requirements of the Sarbanes-Oxley Act, 15 U.S.C. §7241 governing corporate responsibility for financial reports filed with the SEC, defendant Moore, as Biopure's Chief Executive Officer, and defendant Richards, as the Company's Chief Financial Officer, certified that the January 2003 10-Q and April 2003 10-Q did "not contain any untrue statement of a material fact **or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading** with respect to the period covered by this quarterly report...." ¶46 (emphasis added). As noted above, these reports contained statements that were rendered false or misleading because defendants failed to disclose the fact they had been advised about the FDA's Safety Concerns and were aware that FDA approval would likely be delayed or denied as a result. Thus, because they knew those certifications were false, defendants Moore and Richards are liable under Rule 10b-5.

III. Defendants' "Forward-Looking" Statements Regarding the Likelihood of FDA Approval of and Future Revenues from Marketing Hemopure Are Not Protected by Either the Safe Harbor Provisions of the PSLRA or the "Bespeaks Caution" Doctrine

Defendants argue that statements made in press releases, analysts conference

calls, and public filings regarding Biopure and the Hemopure BLA, which plaintiffs allege were materially false and misleading ***when made***, are “forward-looking” statements protected by either the safe harbor provisions of the PSLRA or the “bespeaks caution” doctrine. Biopure Mem. at 16-17, 20-32. The PSLRA provides that a “forward looking” statement, when identified as such, may be non-actionable if accompanied by “meaningful cautionary statements identifying important factors that could cause results to differ materially from those in the forward-looking statement,” or if plaintiff fails to plead it was made with “actual knowledge ... that the statement was false and misleading..” 15 U.S.C. §§77z-2(c)(1), 78u-5(c)(1).

Contrary to defendants’ argument, defendants’ alleged misrepresentations and omissions (i) were not forward-looking statements, (ii) were not accompanied by sufficient cautionary language for “safe harbor” protection, and (iii) were disseminated by defendants with actual knowledge that the statements and omissions were false or misleading when made. Indeed, by knowingly and deliberately failing to disclose the FDA’s Safety Concerns, defendants failed to identify the single most important factor that they knew would cause results to differ materially from their optimistic forward looking statements concerning FDA approval of the Hemopure BLA and anticipated future revenues from the sale of Hemopure. As a result, to the extent their statements were “forward-looking,” neither the safe harbor provisions of the PSLRA nor the “bespeaks caution” doctrine can protect defendants from liability.

A. Defendants’ Alleged Misrepresentations and Omissions Concerning the Status of the Hemopure BLA and Anticipated Revenue From Marketing Hemopure are Not “Forward-Looking” Statements Within the Meaning of

the PSLRA

Simply because a statement touches upon a company's future performance does not automatically make it a "forward-looking" statement under the PSLRA. *In re Boeing Securities Litigation*, 40 F. Supp. 2d 1160, 1169 (W.D. Wash. 1998). As Courts in this District have consistently held, the "safe harbor" defense is unavailable where, as here, "the plaintiffs challenge the truthfulness of a claim regarding **present facts** as opposing to forward looking statements." *In re Number Nine Visual Tech Corp. Securities Litigation*, 51 F. Supp. 2d 1, 19 (D. Mass. 1999) (emphasis in original). See also *Transkaryotic*, 319 F. Supp. 2d at 161-62 ("statements, such as 'We believe the approval of Replagal in the U.S. remains a when not if proposition' ... and 'We believe that the totality of our renal and cardiac data is compelling and that Replagal can be approved on this data' arguably do not fall within the safe harbor provisions. They are statements of present belief that are material and are conceivably in direct contradiction to known facts about the FDA's position with respect to TKT's data and application for marketing approval."); *Sepracor*, 308 F. Supp. 2d at 28 ("the subject matter of the alleged misrepresentations—the results of the animal studies—were a matter of fact rather than conjecture by the time the statements were made. Thus, the statements cannot be characterized as forward-looking, and the safe harbor provisions of the PSLRA do not apply."); *Allaire*, 224 F. Supp. 2d at 336 (statement that "sales were **expected to continue to grow earnings throughout the year** [was] allegedly false because the Defendants already knew that Spectra demand had significantly fallen off because of the product's defects" and "**is the classic type of statement that requires**

full disclosure to avoid being misleading").

As noted above and alleged in detail in the Complaint, defendants misrepresented the status of the Hemopure BLA and their communications with the FDA by failing to disclose the FDA's Safety Concerns, and that FDA approval as well as any future revenue from marketing Hemopure, would unquestionably be delayed or threatened as a result. Defendants learned of the FDA's Safety Concerns in March 2003, at the inception of the Class Period, when the FDA advised them that it was placing a clinical hold on the Trauma Trial. ¶29. Because they omitted this crucial, material fact that bore directly on the future of both the Hemopure BLA and the Company, not one of defendants' alleged misrepresentations and omissions during the Class Period is protected by the safe harbor provisions of the PSLRA. *Transkaryotic*, 319 F. Supp. 2d at 161-62. See also *Irvine v. Imclone Systems, Inc.*, 2003 U.S. Dist. LEXIS 9342, at *3-4 (S.D.N.Y. June 3, 2003) (holding that defendants' alleged misrepresentations concerning current status of clinical studies and FDA approval process were not forward-looking statements); *Amylin*, 2003 U.S. Dist Lexis 7667, at *3-5, *22-23; *Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *25-27.

In particular, defendants' statements that they expect FDA approval of the Hemopure BLA, see ¶¶45, 50, 53, 58, 63, 72, in light of the FDA's Safety Concerns about which they knew but the investing public did not, can receive no safe harbor protection and are therefore actionable. *Transkaryotic*, 319 F. Supp. 2d at 161-62; see also *Amylin*, 2003 U.S. Dist. LEXIS 7667, at *22-23 n.3 ("If a defendant states that it believes or expects that the FDA will approve its drug but had information tending to seriously undermine the accuracy of its statement, the statement is actionable"); *Cell*

Pathways, 2000 U.S. Dist. LEXIS 8584, at *10-11 (“The crux of Plaintiffs’ claim is that the positive statements of [the defendants] … were misleading in that [the defendants] continued to publish positive information concerning the status and development of [the product] while [the defendants] knew of the flaws in the Phase III study”). By the same token, defendants’ alleged statements that they expected to earn substantial revenues in 2004, ¶¶45, 63, were actionable because they knew at the time those statements were made that the FDA’s undisclosed Safety Concerns would significantly delay or even abort the FDA’s approval of the Hemopure BLA.

B. Even If Defendants’ Alleged Misrepresentations Could Be Construed as Forward-Looking Statements, They Are Not Protected by the Safe Harbor Provisions of the PSLRA

To the extent any of defendants’ alleged misstatements or omissions can be deemed to be forward-looking, they do not qualify for safe harbor protection because they were unaccompanied by meaningful cautionary language and were made with actual knowledge of the FDA’s Safety Concerns and their negative impacts on Biopure and the Hemopure BLA. 15 U.S.C. §§77z-2(c)(1), 78u-5(c)(1). Thus, defendants’ reliance on boilerplate disclaimers purporting to disclose risks associated with failure to obtain FDA approval contained in its January 2003 10-Q, April 2003 10-Q and the Registration Statements filed with the SEC, is insufficient. As the Court stated in *Amylin*, “[v]ague or boilerplate disclaimers are insufficient to invoke safe harbor protection.... Rather, cautionary statements must be ‘substantive and tailored to the specific future projections, estimates or opinions ... which the plaintiffs challenge.’” 2003 U.S. Dist. LEXIS 7667, at *20 (quoting *In re Donald J. Trump Casino Securities*

Litigation, 7 F.3d 357, 371-72 (3rd Cir. 1993);¹⁷ see also *Fecht*, 70 F.3d at 108 (“bespeaks caution” doctrine held applicable “only when [defendants] include enough cautionary language or risk disclosure... that ‘reasonable minds’ could not disagree that the challenged statements were not misleading”); *Shaw*, 82 F.3d at 1082 (rejecting “bespeaks caution” argument and citing *Fecht* decision); *Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *27-28 (“Meaningful cautionary language must be substantive and tailored to the specific predictions made in the allegedly misleading statement”). As the Court stated in *Rubenstein v. Collins*, 20 F.3d 160, 267-68 (5th Cir. 1994):

[C]autionary language is not necessarily sufficient, in and of itself, to render predictive statements immaterial as a matter of law.... The appropriate inquiry is whether, under all the circumstances, the omitted fact or the prediction without a reasonable basis ‘is one [that] a reasonable investor would consider significant in [making] the decision to invest, such that it alters the total mix of information available about the proposed investment.’ ... [C]autionary language as such is not *per se* dispositive of this inquiry.

Thus, cautionary language must truthfully address specific, **known** risks, must exhaust the capacity of the positive false statements to mislead investors, **and** must disclose, as defendants failed to do here, then-existing adverse facts. See *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1097 (1991) (cautionary statement must discredit alleged misrepresentations to such an extent that “the risk of real deception

¹⁷As the court stated in *Amylin*: “Individuals commonly ignore such boilerplate warnings because the cautionary language is not sufficiently meaningful. Even if investors read them, merely warnings investors that FDA may not approve the drug tells them something they already know.” See also *ImClone*, 2003 U.S. Dist. LEXIS 9342, at *3-4 (court held cautionary statements that company’s business “was subject to regulation primarily by the FDA,” “noncompliance with applicable requirements can result in refusal to approve product licenses or other applications,” that there are “risks and uncertainties associated with completing pre-clinical trials [and] obtaining and maintaining regulatory approval for such compounds,” and that “actual results may differ materially” from those predicted were insufficient); *Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *28-29 (court found cautionary statements that “future clinical trials may fail” insufficient to warn investors “that the results of the clinical trial reported [in a] press release could be interpreted to show that the drug was ineffective”).

drops to nil"). Indeed, the utterly useless nature of the generic warnings given in the present case, when contrasted with the true status of the FDA's review of the Hemopure BLA at the time, are reminiscent of the late Judge Pollack's famous quote in *In re Prudential Securities, Inc. Limited Partnerships Litigation*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996): "The doctrine of bespeaks caution provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away."

The *PLC* decision, upon which defendants rely, is distinguishable. In *PLC*, plaintiffs alleged that the defendants made hopeful statements concerning FDA approval which were false and misleading because the clinical studies were poorly designed and the clinical data was insufficient for FDA approval of PLC's heart laser. There, the FDA's advisory board had approved the company's protocol for conducting clinical studies (and ultimately approved the product). *PLC*, 41 F. Supp. 2d at 121 & n.11. By contrast, in this case, the FDA **questioned** the safety of Hemopure for use in humans based on adverse events in the clinical orthopedic study submitted with the original Hemopure BLA. Unlike in *PLC*, in light of the FDA's Safety Concerns, the FDA **placed a clinical hold** on Biopure's proposed Trauma Trial and at first delayed then suspended the review process entirely pending Biopure's response to the FDA's request for additional information.

C. Defendants' Alleged Misstatements and Omissions Regarding Prospects for FDA Approval Were Made With Actual Knowledge of the Undisclosed Adverse Facts

Even assuming that defendants' statements concerning the prospects for FDA

approval did qualify as forward looking statements, they are not protected from liability because defendants made them with actual knowledge of the alleged undisclosed adverse facts. See *Amylin*, 2003 U.S. Dist. 7667, at *23 n.3 (“If a defendant states that it believes or expects that the FDA will approve its drug but has information tending to seriously undermine the accuracy of its statement, the statement is actionable”). As demonstrated below, there is absolutely no question that defendants were aware of the FDA’s Safety Concerns from the inception of the Class Period, and the negative impact those concerns could and did have on FDA approval of the Hemopure BLA. Moreover, as further demonstrated below, defendants were on notice that failure to disclose the FDA’s safety concerns was both material and misleading, in light of the decision in *Meyer v. Biopure Corporation*, 221 F.Supp. 2d 195 (D. Mass. 2002), in which the court dismissed claims concerning some of the same defendants’ previous disclosures regarding the Hemopure BLA. In that case, Judge Harrington made clear that omissions regarding the safety of Hemopure would have been actionable. *Id.* at 207.

In addition, defendants claimed to be in constant contact with the FDA regarding the status of the Hemopure BLA throughout most of the Class Period, during which the FDA expressed its Safety Concerns and held up the Trauma Trial. Because defendants had actual knowledge of the FDA’s Safety Concerns and its negative consequences for FDA approval, which undercut their hopeful statements concerning the prospects for obtaining such approval within the predicted timelines, if ever, the PSLRA safe harbor does not apply and defendants’ alleged misstatements are actionable.

IV. The Complaint Alleges Sufficient Facts to Support a Strong Inference of Scienter

The PSLRA requires a plaintiff to plead with particularity facts that support a strong inference of scienter. 15 U.S.C. §78u-4(b)(2). “Scienter may be demonstrated by indirect evidence, and may extend to a form of extreme recklessness that is closer to a lesser form of intent.” *Cabletron*, 311 F.3d at 30. As the court held in *Gelfer v. Pegasystems, Inc.*, 96 F. Supp. 2d 10 (D. Mass. 2000), recklessness may constitute an unreasonable omission, which presents a danger of misleading buyers or sellers, that is either known to the defendant or is so obvious that the defendant must have been aware of it. *Id.* at 13 (quoting *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 198 (1st Cir. 1999)).

Scienter may be further demonstrated by allegations of defendants’ motive and opportunity to commit the alleged fraud. *Cabletron*, 311 F.3d at 39; see also *Aldridge*, 284 F.3d at 82. Indeed, “[t]he First Circuit has indicated its willingness to consider many different types of evidence as relevant to scienter, including ‘the self-interested motivation of defendants in the form of saving their jobs and salaries or jobs.’” *Sepracor*, 308 F. Supp. 2d at 31 (quoting *Greebel*, 194 F.3d at 196). Thus, the First Circuit has held that there is a strong inference of scienter where defendants’ “nondisclosure could hardly have been inadvertent” and the undisclosed fact was “important to their own survival and that of the company.” *Aldridge*, 84 F.3d at 82-83; see also *Cabletron*, 311 F.3d at 39 (held there was a strong inference of scienter where allegations constituted “more than the usual concern by executives to improve financial results; the executives’ careers and the very survival of the company were on the line”).

While the PSLRA requires that a plaintiff allege facts that support a strong inference of scienter, such an inference “need not be irrefutable.” *Cabletron*, 311 F.3d

at 38; *accord Aldridge*, 284 F.3d at 82 (“Inferences must be reasonable and strong – but not irrefutable”); see also *Sepracor*, 308 F. Supp. 2d at 31 (quoting *Cabletron*, 311 F.3d at 38). “Plaintiffs need not foreclose all other characterizations of fact, as the task of weighing contrary accounts is reserved for the fact finder.” *Aldridge*, 284 F.3d at 82 (quoting *Helwig v. Vencor*, 251 F.3d 540, 553 (6th Cir. 2001), cert. denied, 536 U.S. 935 (2002)).

Significantly, the First Circuit has examined the PSLRA’s pleading requirement and held that scienter can be shown by both direct and circumstantial evidence and that the statute neither mandates nor prohibits the use of any particular method to establish the requisite inference of scienter. *Cabletron*, 311 F.3d at 39; *Aldridge*, 248 F.3d at 82; *Greebel*, 194 F.3d at 195. See also *Sepracor*, 308 F. Supp. 2d at 30 (“The First Circuit has adopted a fact-specific, case-by-case approach rather than a rigid formula for alleging scienter”). The First Circuit has emphasized that courts are not to “[categorize] patterns of facts as acceptable or unacceptable to prove scienter,” but instead are to “[analyze] the particular facts alleged in each individual case to determine whether the facts are sufficient to support scienter.” *Greebel*, 194 F.3d at 196; see also *Geffon v. Micrion Corp.*, 249 F.3d 29, 36 (1st Cir. 2001). Most importantly, in determining whether scienter may be inferred, the First Circuit has instructed courts not to look at each allegation in isolation, but rather to consider the totality of the circumstances. See, e.g., *Cabletron*, 311 F.3d at 40 (“Each individual fact about scienter may provide only a brushstroke, but the resulting portrait satisfies the requirement for a strong inference of scienter under the PSLRA”); see also *Friedberg v. Discreet Logic Inc.*, 959 F. Supp. 42, 50 (D. Mass. 1997).

A. Plaintiffs on a Motion to Dismiss Are Entitled to Reasonable Inferences Drawn from the Facts, Including Those from the Wells Notices, in Alleging Scienter

Plaintiffs in this case allege that inferences of the individual defendants' state of mind can be drawn from, inter alia, the facts contained in the Wells Notices. Based on the same facts alleged in the Complaint (i.e., knowledge of the FDA's Safety Concerns and the March 2003 FDA directive placing a hold on the proposed Trauma Trial), the staff of the SEC determined that they should recommend that civil proceedings be brought against Defendants Biopure, Moore and Richman for violation of the federal securities laws due to their failure to disclose the FDA's Safety Concerns during the Class Period. ¶108. In addition, the Complaint alleges that additional inferences are permitted from the fact that after receipt by the SEC staff of the responses of defendants Biopure, Moores and Richman, the staff responded on April 29, 2004 by issuing additional Wells Notices. These notices advised that the SEC staff may also recommend that the SEC bring actions against defendants Sanders, Rausch and Crout, as well as Biopure's general counsel, Jane Kober, for violations of the federal securities laws due to their failure to disclose the FDA's safety concerns during the Class Period.

¶109.

The Biopure Defendants claim that plaintiffs are not permitted inferences from these facts, making the bald statement that pleading facts based upon recommendations by the SEC is not permissible at this juncture.¹⁸ Biopure Mem. at 2.

¹⁸Significantly, defendant Richards urges the Court to draw an opposite inference that he alone among the defendants did not have the requisite scienter because he was the only defendant who was not served with a Wells Notice. Richards Mem. at 2,10-11. The fact that the SEC has not yet served defendant Richards with a Wells Notice does not exonerate him as Richards argues. Richards Mem. at 11. The SEC has neither withdrawn nor taken final action on the recommendations by its staff in the

Defendants make the additional claim that facts contained in the Wells Notices are the only ones plaintiffs have for pleading purposes. Id. Both statements are false. The former is false because Defendants misapprehend and misstate the pleading standards applicable in this Circuit. The latter is false on its face because the defendants have admitted many of the essential allegations of the Complaint, including the central claim contained in the Wells Notice that on March 2003 the FDA placed Biopure's proposed clinical trial of Hemopure in trauma patients on hold based on the FDA's Safety Concerns. ¶37. In fact, defendants do not contest the fact that they did not disclose this highly adverse development.

In addition to the Wells Notice, the inferences of scienter that the plaintiffs here seek to draw are based on a number of distinct facts plead in the Complaint including: huge sales of Biopure stock by insiders (see ¶114); that defendants knew based on a previous opinion of this Court that information indicating that Hemopure was "unsafe" was not only material, but the non-disclosure of such information in itself could give rise to a strong inference of scienter (¶106); the change in Biopure's risk disclosures after the SEC began its investigation (¶¶110-111); in the description of a clinical hold of a competitor's product (¶112); and in the defendants' need to sell shares to the investing public during the Class Period in order to keep the Company operational (¶113.) All of these factors should be considered by the Court.

The First Circuit has reiterated its rejection of a rigid approach in determining whether a complaint had been adequately plead and its adoption of a liberal case by

Wells Notices and presumably its investigation into defendants' wrongdoing is ongoing. To date, the SEC has not expressly exonerated anyone and thus presumably could still serve Richards with a Wells Notice.

case approach :

Each securities fraud complaint must be analyzed on its own facts: there is no one size fits all template. . . . As the Sixth Circuit put it, "In enacting the PSLRA, Congress was concerned with the quantum, not type of proof."

Cabletron, 311 F.3d at 39-40 (citing *Helwig*, 251 F.3d at 551). See *Greebel*, 194 F.3d at 196.

The *Cabletron* case is particularly instructive with regard to the defendants' claim that allegations can not rest on information or inferences drawn from the Wells Notices. In that case this Circuit reviewed the decision of the District Court which granted defendants' motion to dismiss. The lower court decision was based in part on that court's refusal to accept for pleading purposes facts derived from confidential sources. In analyzing this question the First Circuit rejected the highly restrictive approach of the Ninth Circuit in *In Re Silicon Graphics Securities Litigation*, 183 F.3d 970, 985 (9th Circ. 1999), and adopted the flexible approach of the Second Circuit in *Novak v. Kasaks*, 216 F.3d 300, 313 (2d Cir.), cert. denied, 521 U.S. 1012 (2000) which held that:

In our view, notwithstanding the use of the word "all," [section 78u-4(b)(1)] does not require that plaintiffs plead with particularity every single fact upon which their beliefs concerning false or misleading statements are based. Rather, plaintiffs need only plead with particularity sufficient facts to support those beliefs.

Cabletron, 311 F.3d at 30 citing *Novak*, 216 F.3d at 313-14. Judge Lynch of this Circuit went on to state:

The approach we take similar to *Novak*, is to look at all of the facts alleged to see if they "provide an adequate basis for believing that the defendants' statements were false." *Novak*, 216 F.3d at 314. This involves an evaluation, inter alia, of the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the

number of sources, the reliability of the sources, and similar indicia.

Cabletron, 311 F.3d at 29-30. See also *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1102-03 (10th Cir. 2003) (recommending that courts consider, inter alia, coherence, plausibility and specificity of the allegations, whether sources are disclosed and reliability of those sources, and "any other factors that might affect how strongly the facts alleged support a reasonable belief that the defendant's statements were false or misleading"); *In Re Philip Services Corp. Inc.*, 2004 U.S. Dist. Lexis 9261 at *45-46 (S.D.N.Y. May 2004) ("particularized allegations 'provide an adequate basis for believing that [Deloitte's] statements were false,' and make it unnecessary for plaintiffs to disclose the sources of their beliefs at the pleading stage.")

Although the First Circuit was addressing the specific issue of whether confidential sources must be named in a federal securities law complaint to survive a motion on the pleadings, the principles expressed there are *a fortiori* applicable to the instant case where the source is named and is a respected government agency. In short, "what facts and what level of particularity are sufficient to support a plaintiff's beliefs will vary from case to case. . . . The critical threshold is that the allegations must be made in a way that satisfies the court that plaintiff's charge of fraud is not 'unwarranted.'" *In Re Initial Public Offering*, 241 F.Supp. 2d 281, 359 (S.D.N.Y. 2003).

Plaintiffs' allegations that defendants knowingly or recklessly made material misstatements are entirely "coherent" and "plausible" given all the reasons stated above. In light of these circumstances the inference that plaintiffs seek to draw from a recommendation by the staff of the SEC that defendants should be prosecuted by the SEC for violation of federal securities laws should be given deference. Since these

federal securities laws require knowing and or reckless conduct, the fact of this recommendation should be one among several considered by this Court in finding that scienter has been adequately plead. See, e.g., *In re Health Management, Inc. Securities Litigation*, 970 F. Supp. 192, 204 (E.D.N.Y. 1997) (held allegations of SEC's "informal inquiry" into company's alleged accounting improprieties supported "strong inference" of scienter); *In re Hamilton Bankcorp. Securities Litigation*, 194 F. Supp. 2d 1353, 1359 & n.4 (S.D. Fla. 2002) (held government banking agency's investigation into company's alleged accounting improprieties supported strong inference of scienter). "Overall, the accumulated amount of detail the [Complaint] provides tends to be self-verifying; these are not conclusory allegations of fraud, but specific descriptions of the precise means through which it occurred. . . ." *Cabletron*, 311 F.3d at 30. Furthermore, where the dismissal is grounded in Rule 12(b)(6), the facts pleaded in the complaint are taken in the light most favorable to the plaintiff. *Aldridge*, 284 F.3d at 75.

B. Plaintiffs Have Adequately Pled a Strong Inference of Scienter That Defendants Knew about The FDA's Safety Concerns

The law is clear, as evidenced by recent Court of Appeals opinions, including the controlling precedent in this Circuit, that "the fact that . . . defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." *Aldridge*, 284 F.3d at 83; *Florida State Bd. Of Admin. V. GreenTree Fin. Corp.*, 270 F.3d 645, 655 (8th Cir. 2001) ("One of the classic fact patterns giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to information

suggesting that their statements were materially inaccurate."); *Novak*, 216 F.3d at 311 (strong inference of scienter where complaint alleges that defendants knew facts or had access to information suggesting that their public statements were inaccurate); see also *In re Penn Treaty Am. Corp. Sec. Litig.*, 202 F. Supp. 2d 383, 392 (E.D. Pa. 2002) ("Penn Treaty's statements professing its financial health presented a danger of misleading buyers or sellers that was either known to Defendants or was so obvious that Penn Treaty must have been aware of it").

In essence, defendants argue that this Court cannot accept the inference in the Complaint that the Individual Defendants knew about the FDA Safety Concerns based solely on their status as officers and directors. This argument is misplaced both as a matter of law and of fact. That the Individual Defendants had to be aware of the FDA's Safety Concerns is patently apparent. Hemopure was Biopure's only product developed for use in humans and, as discussed above, by March 2003 at the latest, the FDA had communicated to persons at the Company that there were serious safety concerns with the use of Hemopure. In March 2003, the FDA informed persons at the Company that it was halting the proposed Trauma Trial, yet defendants maintain knowledge of this event is not attributable to them. The absurdity of this position is underlined by the defendants' statement in the Company's Annual Report for fiscal 2002 filed with the SEC on January 29, 2003 that: "The Company has identified trauma ***as its next clinical development priority*** and is working with a committee of independent civilian and military trauma experts to broaden its trauma program." ¶26 (emphasis added).

In addition, defendant Moore made clear his active involvement in

communications with the FDA further demonstrating for pleading purposes his knowledge. In a press releases dated April 24, 2003 Moore referred to "our interactions with the FDA" (¶50) and in the press release of May 30, 2003 he stated "We continue to work closely with the agency [the FDA] toward a final decision that will make Hemopure available. . ." (¶59). In a press release of August 21, 2003 Moore stated "We've developed many of our initial response and so far we felt we will be prepared to answer FDA questions." (¶71). These close interactions with the FDA became apparent in Biopure's conference calls with the investing community as defendant Moore in his presentations and responses to questions continued to emphasize active communication with the FDA. In a May 30 conference call referring to the "mid-May" submissions of additional data to the FDA Moore stated "To be clear we were still responding to a new set of questions to the FDA." ¶61. Defendants Richman and Richards were on that call also and voiced no objection to any of the statements.

Moreover, the certifications by Defendant Moore as Biopure CEO and by Defendant Richards as Biopure's Chief Financial Officer filed pursuant to the Sarbanes-Oxley Act and contained in Biopure's January 2003 10-Q and April 2003 10-Q, in addition to certifying that Biopure's January Form 10-Q contains no materially untrue statement, stated that they had designed "disclosure controls and procedures" which would have ensured that they would learn of the FDA Safety Concerns. ¶¶47-48.

Even though the FDA Safety Concerns, which were communicated to Biopure no later than March 2003, stood directly in the path of the development of the Company's "next clinical development priority" - the trauma application of Hemopure and, in fact, of the commercial viability of the Company's sole product, defendants also argue that the

plaintiffs' allegations that the following persons were aware of the FDA Safety Concerns should not be accepted: defendant Rausch, Biopure's Vice-Chairman and Chief Executive Officer, defendant Richman, Senior Vice-President of Regulatory Affairs and Operations who had to have been intimately involved in FDA communications, defendant Sanders, Board Chairman and Board Director defendant Crout. Biopure Mem. at 40-41. These officers and directors had to be aware of pivotal information concerning the Company's sole product for humans in order to perform the minimal obligations of their jobs and it defies credulity that the Chairman of the Board would not have learned of the FDA Safety Concerns and then not informed the full Board of such material adverse developments. In fact, as set forth above, defendants Moore and Richards certified in a SEC filing that defendants had controls in place to inform them of material events. "When a corporate officer signs a document on behalf of the corporation, that signature will be rendered meaningless unless the officer believes that the statement in the documents are true." *Howard v. Everex*, 228 F.3d 1057, 1061 (9th Cir. 2000), cited with approval in *Cabletron*, 311 F.3d at 41. See also *In re Abbot Labs Derivative Stockholder Litig.*, 325 F.3d 795, 808 (7th Cir. 2001) (signing of SEC forms attesting to knowledge and responsibility for compliance with government regulations implies knowledge of breach of duty-continuing violation implies knowledge by Board members). Thus, none of the defendants can now claim they have no culpability because they were not aware of the FDA Safety Concerns, given their affirmative statements that they were aware of corporate developments and their positions on the Board.

Moreover, a standard establishing that defendants knew of the FDA's Safety

Concerns is not the one to which plaintiffs are held. Plaintiffs are entitled for pleading purposes to have all reasonable inferences accepted at this stage. *Aldridge*, 284 F.3d at 82. Since it can not be denied that it was reasonable for the Individual Defendants to be aware of the FDA Safety Concerns plaintiffs have met this burden even without the specific facts described above. See *id.*

In the *Aldridge* case, the First Circuit rested its opinion that scienter had been pled in large part upon the fact that the alleged misrepresentation by defendant corporation, the A.T. Cross Corporation, concerned a new product the success of which was critical to the company's officers keeping their jobs. The similarity to the facts of this case is striking—the success of Hemopure in humans, Biopure's sole product, was critical to the Company's success. That essential truth is not in dispute.

The defendants in the *Sepracor* case, decided by Judge Zobel, similarly argued that scienter can not be inferred from status of the defendant within the Company. In that case, the Company, in its public statements, had ignored potential cardiac related safety side effects of an antihistamine on which the defendant company was very dependent for its success. In determining whether scienter was pled, the Court noted that in this Circuit the pleading must contain a “strong inference” of scienter, but that such inference need not be “irrefutable,” 308 F. Supp. 2d at 31 (citing *Cabletron*, 311 F.3d at 38), and that courts in this Circuit have been willing to consider as evidence probative of scienter the “self interested motivation of defendants in the form of saving their jobs and salaries.” *Id.* at 31 (citing *Greebel*, 194 F.3d at 196). The drug in question, Soltara, was the most promising drug in its pipeline. The complaint in that case alleged that the defendants were highly dependent on that drug for the company's

success and found this fact sufficient in establishing scienter as it was beyond "the usual concern by executives to improve financial results. . . ." *Sepracor*, 308 F. Supp.2d at 31 (citing *Cabletron*, 311 F.3d at 39).

In the instant case, the facts are even much stronger than in *Sepracor* since Hemopure is the Company's **sole** product for humans, thus the rationale regarding the "self-interest" of the defendants is even more compelling. See also *Chalverus v. Pegasystems*, 59 F. Supp.2d 226, 235 (D. Mass. 1999) ("As a matter of law court have held that certain information, particularly facts critical to . . . an important transaction [,] generally are so apparent that their knowledge may be attributed to the Company and its key officers.") (quoting *Epstein v. Itron, Inc.*, 993 F. Supp. 1314, 1326 (E.D. Wash. 1998). See, e.g., *In Re Ancor Communications, Inc.*, 22 F. Supp.2d 999, 1005 (D. Minn. 1998) (knowledge of fact of \$30 million contract could be imputed to officers of company and such knowledge evidences strong inference of scienter); *Rehm v. Eagle Financial Corp.*, 954 F. Supp. 1246, 1256 (N.D. Ill. 1997) (finding defendants' contention that they acted without scienter not credible where subject matter of class period disclosure arose in main area of defendants' business).

Very similar, but less dramatic allegations than those in this case or even in *Sepracor* were upheld as sufficient to show scienter in *Cabletron*. There, plaintiffs alleged that defendants concealed, among other things, some defects that "slowed [the] manufacture" and delayed the commercial availability (but did not prevent U.S. marketing altogether, as in this case) of two of their new products (unlike Biopure here, Cabletron sold many other products, e.g., 311 F.3d at 23). The First Circuit stated:

[T]he complaint identifies concealment of the serious and worsening

deterioration of Cabletron's financial health as a significant motive for the alleged fraud. Cf. Aldridge, 284 F.3d at 83 (scienter supported by corporate officers' understanding that rollout of new product was "important to their own survival and that of the company") Nathenson v. Zonagen, Inc., 267 F.3d 400, 425 (5th Cir. 2001) (scienter for misstatements about patent supported by fact that company's future depended on patent). Indeed, it appears that Levine, a cofounder of the company, was forced out of management as the magnitude of Cabletron's problems began to come to light, thus confirming that these motivating fears were realistic. This is more than the usual concern by executives to improve financial results; the executives' careers and the very survival of the company were on the line.

Cabletron, 311 F.3d at 39 (emphasis added).

Instead of addressing the facts here, defendants ignore the well-pled allegations of the Complaint and maintain simply that, as a matter of law, status of a defendant can not be used to impute knowledge. They cite various cases whose facts bear no resemblance to those before this Court. Defendants cite *In Re Criimi Mae Inc. Sec Litig.*, 94 F. Supp. 2d 652, 661 (D. Md. 2000), for the proposition that the holding of a position of control or authority is in and of itself insufficient to sustain liability against an officer or director. However, in that case the Court granted the defendants' motion to dismiss because "there [were] no facts pled that would give rise to an inference that the defendants issuing the optimistic or reassuring statements knew, or were reckless in not knowing, that the precipitating event . . . was going to occur." Id. at 662. There the court said it had not even been established that the "precipitating event" came prior in time to the false statements. In the instant case, there is no doubt that the "precipitating event," the March 2003 FDA directive to cease clinical trauma trials for Hemopure because of safety concerns, occurred prior to the false and misleading statements made during the Class Period.

Similarly, dismissal in *In Re Pertitus Software Serv., Inc. Sec. Litig.*, 52 F. Supp. 2d 211, 228 (D. Mass. 1999), cited by defendant Richards, was based on either the non-actionability of the statements or the fact that the alleged false statements could not have been made with knowledge of their falsity because no temporal relationship had been set forth, very similar to Criimi Mae. As with these two cases, none of the other cases cited by the defendants address facts anything remotely like those before this Court-a devastating action by a government agency putting on hold the progress of a company's sole product. In contrast in these cases the issues hardly encompass the entire business spectrum of the company as here. See *Shiva II*, 27 F. Supp. 2d 268, 282 (D. Mass. 1998) (primary allegation was that demand for product had weakened); *Zishka v. Amer. Pad & Paper Co.*, 72 Fed Appx. 130, 131-32 (5th Cir. 2003) (The misrepresentations involved strategy of acquiring and integrating other companies. Moreover, this opinion was not published and states on its face it can not be relied upon as precedent except to a very limited degree); and *Smith v. Circuit City Stores, Inc.*, 286 F. Supp. 2d 707, 715 (E.D.Va. 2003) (allegation that defendants concealed the true cost associated with Circuit City's [a large multi-chain electronics retailer] abandonment of leased facilities when it exited the appliance business and that the Defendants failed to disclose the existence and contribution of the company's finance operation to the company's overall performance).

In *Loan v. Federal Deposit Ins. Corp.*, 717 F. Supp. 964, 967 (D. Mass. 1989), cited by defendants, the complaint also lacked facts remotely similar to the allegations of the instant complaint: There “[t]he complaint does not even try to explain how any of the challenged statements were untrue (One of the alleged material

misrepresentations is the following statement, that is most obviously true: 'Banks are extensively regulated under both federal and state law.'"). Merely claiming that a statement is untrue does not make it so. A plaintiff has an obligation to explain what is untrue about each of the challenged statements and cannot merely quote a statement and assert that it is untrue." Plaintiffs here do not disagree with some of the common sense propositions discussed in the above case cited by defendants, but emphasize that none are applicable in the instant case before this Court.

Moreover, as alleged in detail in the Complaint (¶101), in 2002, the Defendants Biopure and Rausch were named as defendants in a federal securities fraud class action entitled, *Thomas H. Meyer, et al. v. Biopure Corporation and Carl W. Rausch*, in the United States District Court for the District of Massachusetts (Civil Action No. 02-10194-EFH). In that action the Plaintiffs alleged that the Defendants had committed securities fraud by failing to disclose defects and deficiencies in the clinical trials conducted for Hemopure. Judge Harrington of this Court, in an Opinion reported at 221 F.Supp. 2d 195, dismissed that complaint. In so doing, Judge Harrington, in language extraordinarily relevant to, and indeed, ironic in light of, the facts in this action, said:

Plaintiffs also plead no basis for inferring that it is highly likely that these alleged omissions were either intentional or highly reckless...***this is not a situation where the facts omitted from the press release are so clearly important that the fact of non-disclosure alone gives rise to a strong inference of scienter, since plaintiffs do not suggest that the "missing" data would show that Hemopure was unsafe....***

222 F. Supp. 2d at 207 (emphasis added).

Hence, even beyond the obvious materiality of the FDA's Safety Concerns, it is plainly evident that defendants knew full well, from Judge Harrington's decision in the

Meyer v. Biopure case, that facts which “...would show that Hemopure was unsafe...” *Id.*, were not only material but “...so clearly important that the fact of non-disclosure alone gives rise to a strong inference of scienter...” *Id.* The Defendants’ failure to disclose the FDA’s Safety Concerns, under these circumstances, creates the strongest possible inference of *scienter*.

The Defendants’ *scienter* is also apparent from the highly significant and material changes which the Defendants made to its disclaimers concerning the risks of failing to obtain FDA approval, **after** the SEC began its investigation of defendants during Biopure’s fiscal quarter ended October 31, 2003. Specifically, this new version of the “risk disclosure” appeared in the Form S-3 registration statement filed with the SEC on August 22, 2003, which was signed by all of the Individual Defendants, except Richman. While still deceptive and misleading because the Defendants continued to omit from it the FDA’s Safety Concerns, the “risk disclosure” statement no longer contained defendants’ false and deceptive statement: “**We believe that our completed pivotal Phase III clinical trials are consistent with the FDA’s most recent guidance on...safety endpoints required for approval of products such as Hemopure for use in surgical indications...**” which the Defendants had repeatedly falsely stated prior to August 22, 2003.¹⁹ ¶106.

¹⁹ Another indicia of the Defendants’ *scienter* is seen from the disparity between defendants’ evasive description of the status of the Trauma Trial, and their straightforward description of the status of clinical trials of one of their potential competitors. As detailed in the Complaint, due to the FDA’s Safety Concerns, the FDA placed the Trauma Trial on clinical hold in March 2003 and twice refused to lift it. ¶__. While defendants fastidiously avoided disclosing the FDA’s clinical hold on Biopure’s proposed Trauma Trial, at his presentation at the ThinkEquity Conference on September 17, 2003, when describing the research efforts of one of Biopure’s potential competitors, defendant Moore had no hesitation in saying:

“**Hemosol is now on a clinical hold. It is not clear whether it will be able to**

**C. Defendants' Insider Trading by Itself Can Establish
Scienter**

In *Sepracor*, the court stated that the facts presented a "close call" because there was no additional evidence of scienter such as insider trading. 308 F. Supp. 2d at 31. By contrast, in the instant case, in addition to the fact that, as in *Sepracor*, the Complaint set forth specific facts that make it "reasonable to believe that the defendants knew that the statements were false or misleading," *id.*(citing *Maldonodo*, 137 F.3d at 9), there is massive insider trading.

Throughout the Class Period, both Biopure and defendant Rausch sold substantial amounts of the Company's stock from which they reaped substantial proceeds, while defendants were in possession of non-public, adverse material information regarding the FDA's concerns about Hemopure and its negative impact on the likelihood that Biopure would receive regulatory approval for Hemopure from the FDA. Between March 2003, when defendants first learned about the FDA's safety concerns regarding Hemopure, and the end of July 2003, Biopure sold almost 12.4 million shares of stock for a total of \$46,314,461. ¶¶94-100. In addition, between April 2003 and the end of August 2003, defendant Rausch, Biopure's Vice Chairman and Chief Technical Officer, sold 246,574 shares of his Biopure stock for \$1,596,900. ¶101.

Plaintiffs' allegations concerning defendants' almost \$48 million in proceeds from insider sales, at a minimum, add to the already extremely strong allegations from which scienter can be inferred. As the First Circuit stated in *Cabletron*, 311 F.3d at 39-40,

resume."

¶107.

after noting plaintiffs' other scienter allegations:

And if these interrelated facts and circumstances still were not enough to give rise to a strong inference of scienter, the complaint adds its allegations of insider trading. Stock sales by insiders can supply evidence of scienter. "The vitality of the inference to be drawn depends on the facts, and can range from marginal to strong." . . . Here, the insider trading allegations add some weight to the other evidence of scienter, and we need not determine whether alone they would suffice.

Courts often look for evidence of "unusual trading or trading at suspicious times or in suspicious amounts" in determining whether sales provide an inference of scienter. *Greebel*, 194 F.3d at 197. "The vitality of the inference to be drawn [from the sales] depends on the facts, and can range from marginal to strong." Id. at 197-98. The fact that defendants Biopure and Rausch sold substantial blocks of shares during the Class Period after defendants became aware of adverse material facts concerning the FDA's Safety Concerns and the FDA's subsequent refusals to lift its hold on the proposed Trauma Trial, at a time when defendants continued to make highly optimistic statements anticipating FDA approval of the Hemopure BLA, are highly suspicious and support a strong inference of scienter. See *In re PerkinElmer, Inc. Sec. Litig.*, 2003 U.S. Dist. LEXIS 17506, at *24-25 (D. Mass. Sept. 30, 2003) (complaint sustained where defendants sold "substantial blocks of stock during the period when, according to the complaint, the problems with [the company's product] were becoming increasing apparent to [defendants]"); *Schlagel v. Learning Tree Int'l.*, 1998 U.S. Dist. LEXIS 20306, at *32 (C.D. Cal. Dec. 23, 1998) ("where stock sales [of \$8.9 million] occurred on the heels of optimistic statements, this constitutes circumstantial evidence that statements were fraudulent when made.").

Contrary to defendants' suggestion, courts have held that there is no bright line

test as to the amount of holdings that must be sold to support an inference of scienter, and that the volume of insider sales is not the only determinative factor. See *Cabletron*, 311 F.3d at 40, citing *Shaw*, 82 F.3d at 1224 (although allegations of smaller-scale insider trading did not show scienter on their own, they "provide some support"). Here, both the timing and amount of the stock sold by the insiders raise suspicions and, thus, together with plaintiffs' other scienter allegations, support a strong inference of scienter.

CONCLUSION

Thus, for all the foregoing reasons, defendants' motions to dismiss should be denied in their entirety.²⁰

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Respectfully submitted by the attorneys for the Plaintiffs and the Class and the Sub-Class,

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²⁰In the event the Court disagrees and chooses to dismiss the Complaint or any portion thereof, plaintiffs respectfully request leave to amend. Fed. R. Civ. P. 15(a).